# NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

#### NOTICE OF PROPOSED RULEMAKING

#### TITLE 9. HEALTH SERVICES

# CHAPTER 13. DEPARTMENT OF HEALTH SERVICES HEALTH PROGRAMS SERVICES

[R05-358]

#### **PREAMBLE**

<u>1.</u>	Sections Affected	Rulemaking Action
	Article 10	Repeal
	R9-13-1001	Repeal
	R9-13-1002	Repeal
	R9-13-1003	Repeal
	Article 11	Repeal
	R9-13-1101	Repeal
	R9-13-1102	Repeal
	R9-13-1104	Repeal
	R9-13-1105	Repeal
	Article 12	Repeal
	R9-13-1201	Repeal

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statutes: A.R.S. §§ 36-2212, 36-2213, 36-2214, 36-2215, 36-2216, and 36-2217

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 4195, October 15, 2004

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

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Telephone: (602) 364-3165
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#### 5. An explanation of the rule, including the agency's reasons for initiating the rule:

A.R.S. Title 36, Chapter 21.1, Article 1 requires the Arizona Department of Health Services (ADHS) to regulate ambulances through certificates of registration, to adopt rules establishing minimum standards for the operation of air ambulance services, and to license air ambulance services.

The rules in 9 A.A.C. 13, Articles 10-12 establish standards for the regulation of air and water ambulances. The rules also include provisions related to ground ambulances. Of the rules in 9 A.A.C. 13, Articles 10-12, ADHS currently enforces only those rules related to registration of air ambulances and insurance requirements for air ambulance services. The remainder of the rules have not been enforced for years.

With the exception of the insurance requirement in R9-13-1001(B)(2), ADHS has not enforced the rules for ambulance service licensure in 9 A.A.C. 13, Article 10 since 1993, when the Arizona Legislature repealed ADHS's statutory authority to license air ambulance services. Although the Arizona Legislature again granted ADHS statutory authority to license air ambulance services in 1995 (not ground or water ambulance services), ADHS did not revive its air ambulance service licensure program using those rules because they were outdated and inconsistent with ADHS's new statutory authority.

ADHS has not applied the rules in 9 A.A.C. 13, Articles 10-12 to water ambulance services or water ambulances since 1983, because there have not been any water ambulances subject to regulation.

ADHS has not applied the rules in 9 A.A.C. 13, Articles 11 and 12 to ground ambulances since 2001, when 9 A.A.C. 13, Article 14 was repealed and new rules for ground ambulance service certificates of necessity and ground ambulance registration were adopted in 9 A.A.C. 25, Articles 9-12.

In this rulemaking, ADHS repeals all of the rules in 9 A.A.C. 13, Articles 10-12 to enable ADHS, in a concurrent rulemaking, to adopt new rules for air ambulance service licensing and air ambulance registration in 9 A.A.C. 25, Articles 7 and 8.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

### 8. The preliminary summary of the economic, small business, and consumer impact:

ADHS will bear the cost of repealing these rules. ADHS, air ambulance services operating in Arizona, and the general public will receive a significant benefit from the repeal of these rules because the repeal will enable ADHS to adopt new rules for air ambulance service licensing and air ambulance registration in 9 A.A.C. 25, Articles 7 and 8, thereby eliminating the potential confusion that currently exists relating to the applicability of many of these rules.

Because ADHS is adopting, in a concurrent rulemaking, rule requirements that are substantially similar to those rule requirements in 9 A.A.C. 13, Articles 10-12 that ADHS is currently enforcing, ADHS does not believe that the repeal of these rules will have any other impacts on air ambulance services or other persons.

# 9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Ed Armijo, Ambulance and Regional Services Section Chief

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Bureau of Emergency Medical Services

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Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

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# 10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceeding to obtain oral comment on the repeal of the rules in 9 A.A.C. 13, Articles 10, 11, and 12, and the adoption of new rules for air ambulance service licensing and air ambulance registration and related time-frames in 9 A.A.C. 25, Articles 7, 8, and 12:

Date: November 16, 2005

**Time:** 10:00 a.m.

Location: 150 N. 18th Ave., Room 540A

Phoenix, AZ 85007

Nature: Oral Proceeding

Written comments on the proposed rulemaking or the preliminary economic, small business, and consumer impact summary may be submitted to either individual listed in items 4 and 9 until the close of record at 5:00 p.m. on November 18, 2005.

# 11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

### 12. Incorporations by reference and their location in the rules:

ADHS is not adding any new incorporations by reference to the rules and is repealing those found in the existing rules.

#### 13. The full text of the rules follows:

#### TITLE 9. HEALTH SERVICES

# CHAPTER 13. DEPARTMENT OF HEALTH SERVICES HEALTH PROGRAMS SERVICES

#### ARTICLE 10. AMBULANCE SERVICE LICENSURE REPEALED

Section

R9-13-1001. License application procedures Repealed

R9-13-1002. Surface, air, and water ambulance service general responsibilities Repealed

R9-13-1003. Air ambulance service general responsibilities Repealed

#### ARTICLE 11. AMBULANCE REGISTRATION CERTIFICATE REPEALED

Section

R9-13-1101. Registration certificate application procedures Repealed

R9-13-1102. Ambulance design requirements Repealed
R9-13-1104. Air ambulance design requirements Repealed

R9-13-1105. Time frames for the Department's Air Ambulance Registration and Registration Renewal Decisions Repealed

#### ARTICLE 12. MISCELLANEOUS REPEALED

Section

R9-13-1201. Waiver Repealed

#### ARTICLE 10. AMBULANCE SERVICE LICENSURE REPEALED

#### **R9-13-1001.** License application procedures Repealed

- A. The ambulance service license shall be valid on the date of issuance and must be renewed annually.
- **B.** A person applying for surface, air and water ambulance service license shall:
  - 1. Complete and submit an application using forms provided by the Division not less than 30 days prior to the requested effective date of the ambulance service license. The application shall contain the name and address of the applicant and owner of the ambulance service, a description of the ambulance to be registered, a roster of EMS personnel to be employed, location and description of the place or places from which the service intends to operate and such other information necessary to determine compliance with applicable statutes and these regulations.
  - 2. Include proof of liability and malpractice insurance to a minimum of \$1,000,000.
  - 3. Submit a complete list of personnel to be utilized as ambulance attendants.
  - 4. Make all equipment, including ambulances, available for inspection prior to issuance of an ambulance service license.
  - 5. Assure that the premises on which ambulances are parked, housed, docked or hangared, and on which ambulance equipment or supplies are stored, are designated as such and made accessible for inspection prior to issuance of an ambulance license.
  - 6. Submit a check or money order, payable to the Arizona Department of Health Services, in the amount of \$100 at the time of application for ambulance service licensure.
  - 7. Submit other information as requested by the Division to assure compliance with these regulations or applicable provisions of law.
- E. License renewal application procedures. Any person applying for surface, air and water ambulance service license renewal shall:
  - 1. Complete and submit an application for ambulance service license renewal not less than 30 days prior to the expiration date of the current license to assure continuity.
  - 2. Apply for renewal using forms provided by the Division and indicate compliance with the requirements as set forth for original license, including inspections.
  - 3. Submit a check or money order payable to the Arizona Department of Health Services, in the amount of \$100 for renewal of ambulance service license at the time of application.

#### **D.** Termination of service

1. Prior to termination of ambulance service, the licensee shall give the Department 30 days notice. Termination of service shall void the ambulance service license.

### E. Suspension and revocation

- 1. After notice and opportunity to be heard is given according to the procedures described in A.R.S. Title 41, Chapter 6, Article 1 and in Chapter 1, Article 1 of this Title, a license may be suspended or revoked upon the grounds set forth in A.R.S. § 36-2215(A).
- 2. If, in the opinion of the Director, there is sufficient information indicating that the licensee has engaged in the activities described in paragraph (1) of this subsection, the Director may request an informal interview with the licensee. If such invitation is refused, or if the interview is attended and the results indicate suspension or revocation of the license might be in order, then a complaint may be issued and a formal hearing may be held in compliance with A.R.S. Title 41, Chapter 6, Article 1 and Chapter 1, Article 1 of this Title.

### R9-13-1002. Surface, air, and water ambulance service general responsibilities Repealed

#### A. All ambulance services shall:

- 1. Display the ambulance service license at the place of business at all times and the license shall not be transferable.
- 2. Respond to all emergency medical situations when dispatched by a responsible party.
- 3. Use fresh and clean linen, cloth or disposable, including blankets for each patient transported. An adequate supply of fresh and clean linen, cloth or disposable, and blankets shall be maintained on the premises.
- 4. Clean and disinfect all equipment coming in contact with the patient.
- 5. Maintain the premises on which ambulances are parked, housed, docked or hangared in a sanitary manner.
- 6. Operate only those ambulances registered by the Department pursuant to Article 11 of these regulations.
- 7. Submit such forms on each patient transported as provided or approved by the Division.
- 8. Submit a written report of all ambulance accidents to the Division within five working days.
- 9. Submit such reports and other information as requested by the Division to assure compliance with these regulations and A.R.S. § 36-2201 through A.R.S. § 36-2231.

#### **B.** Staffing requirements:

- 1. Unless otherwise specified in these regulations, while transporting a patient, each surface ambulance shall be staffed by not less than two certified ambulance attendants, one of whom must be in the patient compartment.
- 2. All ambulance services responding to an emergency medical situation shall assure that only licensed/certified medi-

- eal personnel shall provide treatment of patients at the scene of the medical incident and during patient transfer.
- 3. An ambulance service shall notify the Division in writing of any change in employment of certified ambulance attendant personnel within 15 days of such change.

#### R9-13-1003. Air ambulance service general responsibilities Repealed

- A. All air ambulance services shall: Have pilots and mechanics qualified by training and experience to operate and maintain air ambulances.
  - 1. Have rotor wing pilots with commercial rotoreraft certification with a minimum of 2,000 rotoreraft flight hours as pilot in command. A pilot shall generally have at least 25 hours single engine and 50 hours multi-engine in the specific type of aircraft being used before being allowed to fly as a pilot in command on patient missions.
  - 2. Have fixed wing pilots with a minimum of 2,000 fixed wing flight hours. A pilot shall generally have at least 50 hours in the specific type of aircraft being used before being allowed to fly as a pilot in command on patient missions.
  - 3. Have a pilot, when IFR flights are made, with instrument certification with a minimum of 250 hours of instrument flight time, to include no more than 125 hours of simulated flight time.
  - 4. Have rotor wing mechanics with at least two years experience as a licensed Airframe and Power plant mechanic. The mechanic shall be factory trained or equivalent on the specific type of aircraft before being allowed to work on that aircraft.
- **B.** All ALS air ambulance services, other than neonatal, shall:
  - 1. Have a physician as medical director who by training and experience is qualified in emergency, intensive and trauma care. The medical director shall:
    - a. Supervise the quality of patient care provided by the medical flight crew.
    - b. Provide medical direction and control for the medical flight crew.
    - e. Act as liaison with emergency department physicians to assure continuity of care.
    - d. Monitor and evaluate day to day operations of the air ambulance service.
    - e. Provide individual consultation to medical personnel involved.
    - f. Participate in the training of the medical personnel, including physicians when applicable.
  - 2. Provide for the rapid transport of seriously ill or injured patients who require a high level of intensive care while en
  - 3. Have a medical flight crew with specialized training in intensive and emergency care in the following areas:
    - a. Advanced cardiac life support certification by The American Heart Association or other agency with substantially similar standards approved by the Division.
    - b. Assessment and emergency care of shock and trauma, including multiple trauma, head injuries, burns and other injuries.
    - c. Pediatric emergencies.
    - d. Obstetrical emergencies.
    - e. Behavioral and psychiatric emergencies.
    - f. Altitude physiology.
    - g. EMS communications.
    - h. Aircraft and flight safety.
    - i. All patient equipment on board the air ambulance.
  - 4. Utilize and adhere to medical control plans adopted by the medical director. The medical control plans may include standing orders and shall include the following:
    - a. Treatment protocols.
    - b. Triage protocols.
    - e. Communications protocols.
    - d. Transfer protocols.
    - e. Standing orders.
  - 5. Meet the following training requirements:
    - a. The medical director shall attest in affidavit form, supplied or approved by the Division, that the medical flight crew utilized as ambulance attendants are qualified and have had special training as air ambulance personnel pursuant to R9-13-1003(A)(3).
    - b. The medical director shall implement 20 hours per year of continuing education in the areas set forth in R9 13-1003(A)(3).
    - e. The medical director shall maintain records of training and continuing education on each ambulance attendant and such information shall be available at all times to the Director or his authorized representative.

#### C. All ALS neonatal services shall:

1. Require their medical director attest to neonatal flight nurses proficiency in neonatal resuscitation and general stabilization of the critically ill newborn. The curriculum shall be reviewed and approved by Arizona Department of Health Services. Neonatal nurses are not required to be ACLS certified.

- 2. Require neonatal nurses to have a minimum of two hours of Department approved special training in flight physiology and other special situations encountered in flight that may effect the physiologic functions of the patients and/or interfere with proper function of the medical equipment.
- 3. Require staffing of each ambulance with no less than one qualified neonatal nurse who must be in the patient compartment.
- 4. Utilize additional personnel, if necessary, to properly care for the medical needs of the patient. The choice and qualifications of such additional personnel shall be at the discretion of the medical director.

### **D.** All BLS air ambulance services shall:

- 1. Staff each ambulance with no less than one air ambulance attendant who must be in the patient compartment.
- 2. Utilize additional personnel, if necessary, to properly care for the medical needs of the patient. The choice and qualifications of such additional personnel shall be at the discretion of the referring physician.
- 3. Designate a licensed physician who shall act as medical director for the service.
- 4. Implement ten hours per year of continuing education in the techniques of stabilization and transportation of emergency patients.
- 5. Maintain records of training and continuing education on each ambulance attendant and such information shall be available at all times to the Director or his authorized representative.
- 6. Not be utilized for the transportation of patients in need of Advanced Life Support services.

# ARTICLE 11. AMBULANCE REGISTRATION CERTIFICATE REPEALED

# R9-13-1101. Registration certificate application procedures Repealed

- A. Any person applying for an ambulance registration certificate shall:
  - 1. Complete and submit an application using forms provided by the Division. The application shall contain the information required in R9-13-1001(B)(1).
  - 2. Submit a check or money order payable to the Arizona Department of Health Services in the amount of \$50 per ambulance.
  - 3. Make each ambulance to be registered available for inspection prior to the issuance of a registration certificate.

#### **B.** Registration certificate provisions

- 1. The registration certificate shall not be transferable to any other ambulance.
- 2. The registration shall be prominently displayed within the ambulance.
- 3. The registration shall be valid from date of issue and must be renewed annually.
- C. Certificate renewal application procedures. Any person applying for an ambulance registration certificate shall:
  - 1. Complete and submit an application for renewal of an ambulance registration certificate to the Division not less than 30 days prior to expiration of current certificate to assure continuity.
  - 2. Apply for renewal using forms provided by the Division and indicate compliance with the requirements as set forth for original registration, including ambulance inspections.
  - 3. Submit a check or money order payable to the Arizona Department of Health Services, in the amount of \$50 for renewal of the current registration certificate at the time of application.
  - 4. Submit other information as requested by the Division to assure compliance with these regulations or applicable provisions of the law.

# **D.** Termination of registration certificate

- 1. Prior to termination of ambulance service, the certificate holder shall give the Department 30 days' notice. Termination of service shall void the registration certificate.
- 2. A registration certificate issued under this Section terminates upon any change of ownership or control of a ambulance.
- 3. Following any change of ownership, the ambulance shall be registered by the new owner before the ambulance may again be operated in the state.

# E. Suspension and revocation

- 1. Emergency suspension. Pursuant to A.R.S. § 41 1012(C) an ambulance registration certificate may be summarily suspended if the Division finds that the ambulance is not in compliance with the regulations in this Article and such non-compliance constitutes an emergency that imperatively requires immediate action to protect the health or safety of patients or attendants transported in the ambulance.
- 2. Suspension or revocation following a hearing
  - a. After notice and opportunity to be heard is given according to the procedures described in A.R.S. Title 41, Chapter 6, Article 1 and in Chapter 1, Article 1 of this Title, a registration certificate may be suspended or revoked upon the following grounds:
    - i. The certificate holder has in any way provided false information to the Division for the purpose of evaluation or registration.

- ii. That the certificate holder has failed to conform with the applicable requirements of A.R.S. Title 36, Chapter 21.1, Articles 1 or 2 and the regulations in this Article.
- b. If in the opinion of the Director, there is sufficient information indicating that the certificate holder has engaged in activities described in paragraph (1) of this subsection, the Director may request an informal interview with the certificate holder. If such invitation is refused, or if the interview is attended and the results indicate revocation of certificate might be in order, then a complaint may be issued and a formal hearing may be held in compliance with A.R.S. Title 41, Chapter 6, Article 1 and Chapter 1, Article 1 of this Title.

#### R9-13-1102. Ambulance design requirements Repealed

#### A. All ambulances shall:

- 1. Have access doors to the patient compartment of sufficient size to permit the safe loading and unloading of a person occupying a litter or stretcher, in the supine position, without interrupting life support measures.
- 2. Be temperature regulated to assure patient and attendant comfort.
- 3. Be equipped with appropriate operable lights and sirens for an emergency ambulance in accordance with Chapter 6, Article 2, A.R.S. § 28-624.
- 4. Only display ambulance markings that accurately reflect the level of care provided.
- 5. Be equipped with approved safety belts and anchorage for all occupants which shall comply with 49 CFR 571.208, 571.209 and 571.210.
- 6. Have sufficient lighting available for patient observation in the patient compartment.
- 7. Be equipped with a two way radio capable of direct communication with a hospital when transporting a patient. The radio shall be compatible with the state EMSCOM system established by A.R.S. § 41-1835.
- 8. Have an electrical system capable of supporting any auxiliary equipment on, or in, the ambulance without the threat of overload or system failure.

### **B.** Minimum equipment and supply requirements

- 1. All responding ambulances shall contain the medical equipment and supplies recommended by the American College of Surgeons in "Essential Equipment For Ambulances", revised June, 1981, which is on file at the Department and a copy of which has been submitted to the Secretary of State.
- 2. In addition to the medical equipment and supplies required in subsection (B)(1) above, all ALS ambulances staffed by paramedies shall contain the following additional equipment:
  - a. Defibrillator
  - b. Electrocardiac monitor/tekenetry radio transmission
  - e. Paramedic Drug Box approved by the Department, pursuant to R9-13-402(B)(4).
  - d. Laryngoscope and assorted airway devices including endotracheal tubes.
- 3. All ambulances utilized to provide Advanced Life Support services shall contain the drugs required pursuant to the Arizona Department of Health Services Paramedic and IEMT Drug List, revised July 8, 1982, which is on file at the Department and a copy of which has been submitted to the Secretary of State.

# R9-13-1104. Air ambulance design requirements Repealed

#### A: Fixed wing aircraft shall meet or exceed the following minimum requirements:

- 1. The aircraft shall have appropriate navigational radio and radar equipment for visual flight rules and, if necessary, instrument flight rules. Aircraft shall be equipped with radio headsets for all pilot crew members for intracockpit communication.
- 2. If the aircraft is to be used for the delivery of basic life support, the patient compartment design shall have sufficient space to accommodate at least one air ambulance attendant and one litter patient.
- 3. If the aircraft is to be used for the delivery of advanced life support care and techniques, the patient compartment design shall have sufficient interior space to accommodate at least one medical flight crew member with space for an additional attendant or medical technician, if indicated by the patient's condition, and one litter patient.
- 4. Safety belts shall be provided for all flight crew attendants. Safety and security restraints shall be provided for all equipment on board. Medical personnel shall be able to wear safety belts when working on the patient. The safety belt may be loosely attached to the attendant so as not to inhibit treatment of the patient.
- 5. If the aircraft is utilized for the delivery of neonatal life support and for the transportation of patients who require such care, transports shall be made in pressurized aircraft only. The interior design shall provide space for a minimum of one neonatal transport module and necessary life support equipment.
- 6. The cabin shall be large enough to allow unrestricted access to the patient while in flight by appropriate air ambulance attendants or medical flight crew members, as well as adequate room for medical equipment and supplies. The upper surface of the litter shall not be less than 24 inches from the ceiling of the aircraft, or the undersurface of another litter.
- 7. Ambulance shall be capable of pressurization for patient transport under medical conditions that require pressurization as determined by the air ambulance medical director under the Guidelines on Conditions Requiring Pressurized

Aircraft set forth by the Arizona Department of Health Services, dated December, 1982, which is on file at the Department and a copy of which has been submitted to the Secretary of State.

- 8. Ambulances providing Advanced Life Support services shall have the following additional equipment:
  - a. Ventilator equipped with a means of delivering positive-end-expiratory pressure.
  - b. Transdermal PO2 monitor.
  - c. Intravenous infusion pump.
- **B.** Air ambulance lighting and electrical power sources. All electrically operated medical equipment used on the aircraft shall have an external alternative compatible power source available.
- C. Rotary wing aircraft shall meet or exceed the following minimum requirements:
  - 1. Aircraft shall have appropriate navigational, radios, and radar equipment for visual flight rules and, if necessary, instrument flight rules. Aircraft shall be equipped with radio headsets for all erew members for intracraft communication.
  - 2. If the aircraft is to be used for the delivery of basic life support, the patient compartment design shall have sufficient space to accommodate at least one air ambulance attendant and at least one litter patient with capability for provision of a second temporary litter. The second litter may be stored.
  - 3. If the aircraft is to be used for the delivery of advanced life support care and techniques the patient compartment design shall have sufficient interior space to accommodate at least one medical flight crew member with space for an additional member if indicated by the patient's medical condition and at least one litter patient with the patient area so configured that advanced life support techniques may be performed for one person during transport.
  - 4. Aircraft providing Advanced Life Support services shall have the following additional equipment:
    - a. Ventilator equipped with a means of delivering positive end expiratory pressure.
    - b. Transdermal PO<sub>2</sub> monitor.
    - e. Intravenous infusion pump.
  - 5. If the aircraft is utilized for the delivery of neonatal life support and for the transportation of patients who require such care, then the interior design shall provide space for a minimum of one neonatal transport module and necessary, life support equipment.
- **D.** Rotary wing warning devices
  - 1. Visible warning devices shall be installed on the underside of the aircraft to provide adequate day/night emergency warning.
  - 2. Audible warning devices shall be installed to provide adequate and external voice communications.
- E. Rotary wing lighting
  - 1. The aircraft shall be equipped with a remote controlled search light.
  - 2. The aircraft shall be equipped with a light that illuminates the tail rotor area.
- F. Minimum equipment and supply requirements. All air ambulances shall contain the medical equipment and supplies recommended by the American College of Surgeons in "Air Ambulance Operations", dated February, 1980, which is on file at the Department and a copy of which has been submitted to the Secretary of State.

# R9-13-1105. Time-frames for the Department's Air Ambulance Registration and Registration Renewal Decisions Repealed

The Department shall approve or deny an application under this Article according to 9 A.A.C. 25, Article 12.

### ARTICLE 12. MISCELLANEOUS REPEALED

#### R9-13-1201. Waiver Repealed

- Any of the provisions of these regulations relating to Ambulance Design Requirements as stated in R9-13-1102, R9-13-1103 and R9-13-1104, may be waived by the Director where the public need so requires and where such waiver will not endanger the health, safety and welfare of the public.
- **B.** The waiver available under this rule is prospective in effect only, and, if a waiver is desired, it must be applied for in writing and granted in writing before any ambulance service or person may operate contrary to the Ambulance Design Requirements in R9-13-1102 through R9-13-1105.

# NOTICE OF PROPOSED RULEMAKING

#### TITLE 9. HEALTH SERVICES

# CHAPTER 24. DEPARTMENT OF HEALTH SERVICES ARIZONA MEDICALLY UNDERSERVED AREA HEALTH SERVICES

[R05-343]

#### **PREAMBLE**

<u>1.</u>	Sections Affected	Rulemaking Action
	Article 1	Repeal
	R9-24-101	Repeal
	R9-24-102	Repeal
	R9-24-201	Amend
	R9-24-202	Amend
	R9-24-203	Amend
	Table 1	Amend
	R9-24-204	Amend
	R9-24-205	New Section
	R9-24-301	Amend
	R9-24-302	Amend

# 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F) Implementing statutes: A.R.S. §§ 36-2352 and 36-2354

#### 3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 11 A.A.R. 2450, July 1, 2005

Notice of Rulemaking Docket Opening: 11 A.A.R. 2981, August 5, 2005

#### 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

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# 5. An explanation of the rule, including the agency's reasons for initiating the rule:

A.R.S. § 36-2352 requires the Department to designate Arizona medically underserved areas (AzMUAs). A.R.S. § 36-2354 authorizes the Department to establish the functions of coordinating medical providers who supervise the medical care offered at a medical clinic in an AzMUA. The Department originally made AzMUA and coordinating medical provider rules in 1978. In 1994, the legislature changed the statutory scheme for AzMUA designation. The

Department's AzMUA designation program has been consistent with the statutory scheme since 1994, although the rules were not changed until 2001.

In this rulemaking, the Department is revising the AzMUA and coordinating medical provider rules in 9 A.A.C. 24 that became effective in January 2001. The Department is making revisions in accordance with the five-year-review report approved by the Governor's Regulatory Review Council on December 7, 2004. Additionally, the Department is consolidating 9 A.A.C. 24, Articles 1 and 2 to simplify the structure and improve the accessibility of the AzMUA rules.

The Department is repealing 9 A.A.C. 24, Article 1, General, including R9-24-101, Definitions, and R9-24-102, Time-frames. Definitions of non-statutorily defined terms and the boundary change request time-frames are being remade in Article 2. The new AzMUA rules structure will benefit the public by making the rules easier to use.

For 9 A.A.C. 24, Article 2, the Department is remaking in R9-24-201 definitions of terms defined in current R9-24-101 that are not included in A.R.S. § 36-2351, improving R9-24-201 definitions, and adding to R9-24-201 definitions of previously undefined terms. These changes will make the rules more understandable to the public. The Department is making new R9-24-205, containing the R9-24-102 time-frames with technical changes. These technical changes will improve the rule, although the Department has not received any primary care area boundary change request according to R9-24-204(C). No substantive changes are being made in the AzMUA designation process in R9-24-202, R9-24-203, and Table1 or in the primary care area boundary determination process in R9-24-204.

For 9 A.A.C. 24, Article 3, the Department is adding definitions of previously undefined terms to increase understandability. Additionally, the Department is making substantive changes to R9-24-302, dealing with the coordinating medical provider functions. Some of these changes result from the different scopes of practice of registered nurse practitioners and physician assistants. No AzMUA has ever had a coordinating medical provider.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review and does not propose to rely on any study for this rulemaking.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

To clarify the structure and improve the accessibility of the AzMUA rules, the Department is repealing 9 A.A.C. 24, Article 1, General, including R9-24-101, Definitions, and R9-24-102, Time-frames. Definitions of non-statutorily defined terms and the boundary change request time-frames are being remade in Article 2. The Department believes that this structural change will benefit the public.

For 9 A.A.C. 24, Article 2, the Department is remaking in R9-24-201 definitions of terms defined in current R9-24-101 that are not included in A.R.S. § 36-2351, improving R9-24-201 definitions, and adding to R9-24-201 definitions of previously undefined terms. The Department is making new R9-24-205, containing the R9-24-102 time-frames with technical changes. The Department is not making any substantive changes to R9-24-202, R9-24-203, Table 1, or R9-24-204. The Department has not received any primary care area boundary change request according to R9-24-204(C).

For 9 A.A.C. 24, Article 3, the Department is adding definitions of previously undefined terms in R9-24-301 and making some substantive changes to R9-24 302. However, no AzMUA has ever had a coordinating medical provider.

Under the existing rules, the Department incurs substantial costs (\$10,000 or more) to operate the AzMUA designation program, including preparation of the primary care index. The Department believes that the revisions to the AzMUA and coordinating medical provider rules will not increase the Department's costs. The Department also believes that revisions to the AzMUA designation rules will not impose any direct costs on any other individual or entity.

The Department's AzMUA program and its rules indirectly result in substantial benefits or losses to a primary care area and to medical facilities or individuals in the primary care area. A.R.S. § 36-2371(E) gives primary care provider loan repayment program priority to rural areas with an AzMUA designation or assigned to a high-degree-of-shortage group according to federal regulations. These regulations are currently located at 42 CFR Part 5, Appendix A to Part 5, Criteria for Designation of Areas Having Shortages of Primary Medical Care Professional(s). A primary care area with an AzMUA designation also is eligible for health crisis fund monies for "basic health services delivery disruptions, caused by unforeseen circumstances" under A.R.S. § 36-797. A primary care area with an AzMUA designation may receive the Department's assistance to recruit a coordinating medical provider under A.R.S. § 36-2353. To the Department's knowledge, this assistance has not occurred, and no AzMUA has used the rules in 9 A.A.C. 24, Article 3.

Non-Department programs that require AzMUA designation include the Arizona medical student loan program under A.R.S. Title 15, Chapter 13, Article 7; and priority consideration by the University of Arizona College of Medicine

for applicants who indicate their willingness to practice in AzMUAs under A.R.S. § 15-1751. Additionally, under A.R.S. § 48-2201 a health service district may be established only in an area with an AzMUA designation. The Department is aware of only one health service district in the state, the Ajo-Lukeville Health Service District.

Under the revised rules, the Department's methodology for AzMUA designation under 9 A.A.C. 24, Article 2 will continue to result in some annual variation because the indicators established in A.R.S. § 36-2352(A) measure variable demographics.

Under the revised rules, benefits and losses to primary care areas and to medical facilities or individuals in primary care areas will remain indirect, resulting from the need for AzMUA designation for participation in programs under statutes other than A.R.S. § 36-2352. Direct costs related to designating AzMUAs will continue to arise from the Department's performance of its statutory functions under A.R.S. Title 36, Chapter 24.

The Department, external stakeholders, and members of the public may experience minimal costs and benefits (less than \$1000) from the time-frame rule if the Department receives a primary care area boundary change request according to R9-24-204(C). The Department, external stakeholders, and members of the public may experience undetermined costs and benefits from the coordinating medical provider rules if these rules are ever used. The benefits from 9 A.A.C. 24 as revised will continue to outweigh the costs.

# 9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Myriam Vega, Office Chief

Address: Office of Health Systems Development

Department of Health Services 1740 W. Adams, Room 410

Phoenix, AZ 85007

Telephone: (602) 542-1219
Fax: (602) 542-2011
E-mail: vegami@azdhs.gov

Or

Name: Kathleen Phillips, Rules Administrator

Address: Office of Administrative Rules

Arizona Department of Health Services

1740 W. Adams, Suite 202

Phoenix, AZ 85007

Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: phillik@azdhs.gov

# 10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has not scheduled an oral proceeding. Until the close of record, a person may submit a written request for an oral proceeding to the individuals listed in items #4 and 9.

Until the close of record, a person may submit written comments on the proposed rules or the preliminary economic, small business, and consumer impact summary to the individuals listed in items #4 and 9.

CLOSE OF RECORD	
5:00 p.m., November 1, 2005	

# 11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

#### 12. Incorporations by reference and their location in the rules:

The first table in Appendix B. Ambulatory Care Sensitive Conditions to "Using Administrative Data to Monitor Access, Identify Disparities, and Assess Performance of the Safety Net," in *Tools for Monitoring the Health Care* 

Safety Net, AHRQ Publication No. 03-0027, September 2003, Agency for Healthcare Research and Quality, Rockville, MD, incorporated at R9-24-201(3).

#### 13. The full text of the rules follows:

#### TITLE 9. HEALTH SERVICES

# CHAPTER 24. DEPARTMENT OF HEALTH SERVICES ARIZONA MEDICALLY UNDERSERVED AREA HEALTH SERVICES

#### ARTICLE 1. GENERAL REPEALED

Section	
R9-24-101.	Definitions Repealed
R9-24-102.	Time-frames Repealed

#### ARTICLE 2. ARIZONA MEDICALLY UNDERSERVED AREAS

Section	
R9-24-201.	Definitions
R9-24-202.	Arizona Medically Underserved Area Designation
R9-24-203.	Primary Care Index
Table 1.	Primary Care Index Scoring
R9-24-204.	Primary Care Area Designation Boundaries Determination
R9-24-205.	Repealed Time-frames

#### ARTICLE 3. COORDINATING MEDICAL PROVIDERS

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R9-24-301. Definitions R9-24-302. Functions

#### ARTICLE 1. GENERAL REPEALED

#### **R9-24-101.** Definitions Repealed

In this Chapter, unless otherwise specified:

- 1. "Arizona medically underserved area" means a primary care area that is designated by the Secretary of the United States Department of Health and Human Services as a health professional shortage area or that is designated by the Department using the methodology described in A.A.C. R9-24-203.
- 2. "Days" means calendar days, excluding the day of the act, event, or default from which a designated period of time begins to run and excluding the last day of the period if it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day that is not a Saturday, a Sunday, or a legal holiday.
- 3. "Department" means the Arizona Department of Health Services.
- 4. "Health professional shortage area" means a geographic region designated by the Secretary of the United States Department of Health and Human Services under 42 U.S.C. § 254e as a primary medical care health professional shortage area.
- 5. "Physician" has the same meaning as in A.R.S. § 36-2351.
- 6. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
- 7. "Primary care area" means a geographic region designated as a primary care area by the Department under A.A.C. R9-24-204.
- 8. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.

### R9-24-102. Time-frames Repealed

- A. The overall time-frame described in A.R.S. § 41-1072 for a request for boundary change under A.A.C. R9-24-204 is 90 days. The person requesting a boundary change and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.
- B. The administrative completeness review time-frame described in A.R.S. § 41-1072 for a request for boundary change

under A.A.C. R9-24-204 is 30 days and begins on the date that the Department receives a request for boundary change.

- The Department shall mail a notice of administrative completeness or deficiencies to the person requesting a boundary change within the administrative completeness review time frame.
  - a. A notice of deficiencies shall list each deficiency and the information and documentation needed to complete the request for boundary change.
  - If the Department issues a notice of deficiencies within the administrative completeness review time frame, the administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice is issued until the date that the Department receives the missing information from the person requesting a boundary change.
  - e. If the person requesting a boundary change fails to submit to the Department all of the information and documents listed in the notice of deficiencies within 30 days from the date that the Department mails the notice of deficiencies, the Department shall consider the request for boundary change withdrawn.
- 2. If the Department issues an approval to the person requesting a boundary change during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.
- C. The substantive review time frame described in A.R.S. § 41 1072 is 60 days and begins on the date of the notice of administrative completeness.
  - 1. The Department shall mail written notification of approval or denial of the request for boundary change to the person requesting a boundary change within the substantive review time frame.
  - 2. During the substantive review time-frame, the Department may make 1 comprehensive written request for additional information, unless the Department and the person requesting a boundary change agree in writing to allow the Department to submit supplemental requests for information.
  - 3. If the Department issues a comprehensive written request or a supplemental request for information, the substantive review time-frame and the overall time-frame shall be suspended from the date that the Department issues the request until the date that the Department receives all of the information requested. If the person requesting a boundary change fails to submit to the Department all of the information and documents listed in the comprehensive written request or supplemental request for information within 30 days from the date that the Department mails the comprehensive written request or supplemental request for information, the Department shall consider the request for boundary change withdrawn.
  - The Department shall approve a request for boundary change under A.A.C. R9-24-204 unless the Department determines that the resulting primary care area does not comply with A.A.C. R9 24 204(A).

### ARTICLE 2. ARIZONA MEDICALLY UNDERSERVED AREAS

#### R9-24-201. **Definitions**

In addition to the definitions in A.R.S. § 36-2351, the following definitions apply in this Article, unless otherwise specified:

- "Act, event, or default" means an occurrence or the failure of something to occur. "Agency" has the same meaning as in A.R.S. § 41-1001.
- 1.3. "Ambulatory care sensitive conditions" means the illnesses listed as ambulatory care sensitive conditions in Ambulatory Care Access Project, United Hospital Fund of New York, Final Code Specifications for "Ambulatory Care Sensitive" Conditions, "Referral Sensitive" Surgical and Medical Conditions, "Marker" Conditions (July 30, 1991, which is in the first table of Appendix B. Ambulatory Care Sensitive Conditions to "Using Administrative Data to Monitor Access, Identify Disparities, and Assess Performance of the Safety Net," in Tools for Monitoring the Health Care Safety Net, AHRO Publication No. 03-0027, September 2003, Agency for Healthcare Research and Quality, Rockville, MD (no later amendments or editions), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from United Hospital Fund, 350 5th Avenue, 23rd Floor, New York, NY 10118-2399. This incorporation by reference contains no future editions or amendments. the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services at:
  - AHRQ Publications Clearinghouse, PO Box 8547, Silver Spring, MD 20907;
  - (800) 358-9295; or
  - http://www.ahrq.gov/data/safetynet/billappb.htm:
- "Arizona Medical Board" means the agency established by A.R.S. § 32-1402 to regulate physicians licensed under A.R.S. Title 32, Chapter 13.
- "Arizona medically underserved area" means:
  - A primary care area or part of a primary care area with the designation described in R9-24-202(1), or
  - A primary care area with the designation described in R9-24-202(2).
- "Arizona Regulatory Board of Physician Assistants" means the agency established by A.R.S. § 32-2502 to regulate physician assistants.
- "Arizona State Board of Nursing" means the agency established by A.R.S. § 32-1602 to regulate nurses and nursing

- assistants.
- 2.8. "Birth life expectancy" means the average life span at the time of birth as published in according to the most recent United States Life Tables by U.S. life expectancy data in the National Vital Statistics Reports of the National Vital Statistics System, available on the web site of the National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, at http://www.cdc.gov/nchs/fastats/lifeexpec.htm.
- 9. "Board of Osteopathic Examiners in Medicine and Surgery" means the agency established by A.R.S. § 32-1801 to regulate physicians licensed under A.R.S. Title 32, Chapter 17.
- 10. "Boundary change" means a re-determination of the geographic limits of a primary care area.
- 11. "Census block" means the smallest unit of census geography that may:
  - a. In a city, correspond to an area that is bounded by streets, or
  - b. In a rural area, include many square miles and have some boundaries that are not streets.
- 12. "Days" means calendar days:
  - a. Excluding the day of the act, event, or default that triggers a time-frame;
  - b. Excluding the last day of a time-frame if it is a Saturday, a Sunday, or a legal holiday; and
  - c. If the last day of a time-frame is excluded under subsection (11)(b), including the next day that is not a Saturday, a Sunday, or a legal holiday.
- 3.13. "Family unit" means:
  - a. A group of Two or more individuals residing together related by birth, marriage, or adoption who are related by birth, marriage, or adoption live together; or
  - b. An One individual who does not reside live with any individual to whom the individual is anyone related by birth, marriage, or adoption.
- 4. 14. "Full-time" means providing primary care services for at least 40 hours during the 7-day period between a Sunday at 12:00 a.m. midnight and the next Saturday at 11:59 p.m. Sunday at 12:00 midnight.
- 15. "Health organization" means:
  - a. A person or entity that provides medical services;
  - b. A third party payor defined in A.R.S. § 36-125.07(C); or
  - c. A trade or professional association described in paragraph (3), (4), (5), or (6) of Section 501(c) of the Internal Revenue Code, 26 USC 501(c), that is exempt from federal income taxes.
- 5. "Hospital" has the same meaning as in A.R.S. § 36-2351.
- 6. "HPSA" means health professional shortage area.
- 16. "Indian reservation" has the same meaning as in A.R.S. § 11-801.
- 17. "Legal holiday" means a state service holiday listed in A.A.C. R2-5-402.
- 18. "Local planning personnel" means individuals who develop programs related to the delivery of and access to medical services for places or areas in the state.
- 7. 19. "Low-weight birth" means the live birth of an infant weighing less than 2500 grams or 5 five pounds, 8 eight ounces.
- 20. "Medical services" has the same meaning as in A.R.S. § 36-401.
- 8. 21. "Mobility limitation" means a physical or mental condition that:
  - a. Has lasted for 6-or more at least six months,
  - b. Makes it difficult Impairs an individual's ability to go outside the home individual's residence alone, and
  - c. Is not a temporary health problem such as a broken bone that is expected to heal normally.
- 22. "Motor vehicle" has the same meaning as in A.R.S. § 28-101.
- 9. "Office of Vital Records" means the office of the Department component that prepares, publishes, and disseminates vital records.
- 23. "Person" has the same meaning as is A.R.S. § 41-1001.
- 24. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
- 25. "Political subdivision" means a county, city, town, district, association, or authority created by state law.
- 10.26. "Population" means the total of permanent residents number of residents of a place or an area, according to:
  - <u>a.</u> the <u>The</u> most recent decennial census <u>published</u> <u>prepared</u> by the <u>United States</u> <u>U.S.</u> Census Bureau <u>and available</u> <u>at http://www.census.gov;</u> or
  - <u>b.</u> <u>according to the The most recent Population Estimates for Arizona's Counties and Incorporated Places and Balance of County <u>published prepared</u> by the <u>Arizona Department of Economic Security and available at http://www.workforce.az.gov/?PAGED=67&SUBID=137.</u></u>
- 11.27. "Poverty level threshold" means the annual income for a family unit of a particular size in the poverty guidelines updated annually in the Federal Register by the United States Department of Health and Human Services calendar year income relative to family unit size that:
  - a. Determines an individual's poverty status,
  - b. Is defined annually by the U.S. Census Bureau, and
  - c. <u>Is available for the most recently completed calendar year at http://www.census.gov/hhes/poverty/threshld.html.</u>

# **Notices of Proposed Rulemaking**

- 28. "Primary care area" means a geographic region determined by the Department under R9-24-204.
- 29. "Primary care HPSA" means primary care health professional shortage area designated by the U.S. Department of Health and Human Services under 42 USC 254e, 42 CFR 5.1 through 5.4, and 42 CFR Part 5, Appendix A.
- 12.30. "Primary care index" means the document in which the Department designates primary care areas as medically underserved by using the methodology described in A.A.C. according to R9-24-203 and Table 1.
- 13.31."Primary care provider" means a physician, <u>a</u> physician assistant, or <u>a</u> registered nurse practitioner <del>providing direct</del> <del>patient care</del> who:
  - a. Except for emergencies, is an individual's first health care contact; and
  - <u>b.</u> <u>Provides primary care services</u> in general or family practice, general internal medicine, pediatrics, or obstetrics and gynecology.
- 14-32. "Primary care services" means health care provided by a primary care provider, including:
  - a. <u>Illness and injury pre</u>vention.
  - b. Health promotion and education,
  - c. <u>Identification of individuals at special risk for illness</u>,
  - d. Early detection of illness.
  - e. Treatment of illness and injury, and
  - <u>f.</u> Referral to specialists.
- 33. "Primary care services utilization pattern" means a summary, based on the factors and data considered in R9-24-204(A)(2), of the distribution of primary care services.
- 34. "Registered nurse" has the same meaning as in A.R.S. § 32-1601.
- 35. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.
- 36. "Resident" means an individual who lives and sleeps in a place or an area most of the time.
- 15. 37. "Self-care limitation" means a physical or mental condition that:
  - a. Has lasted for 6 or more at least six months;
  - b. Makes it difficult to take care of personal needs Impairs an individual's ability to perform activities such as dressing, bathing, or moving around inside the home individual's residence; and
  - c. Is not a temporary health problem such as a broken bone that is expected to heal normally.
- 38. "Topography" means the surface configuration of a place or region, including elevations and positions of the physical features.
- 39. "Travel pattern" means a prevalent flow of motor vehicles resulting from:
  - a. The configuration of streets, and
  - b. The location of residential and nonresidential areas.
- 40. "Value" means a number within a value range.
- 41. "Value range" means, for a criterion listed in R9-24-203(B) and Table 1, a measurement:
  - a. Consisting of a scale between upper and lower limits, except for the supplementary criteria score under R9-24-203(B)(12); and
  - b. To which Table 1 assigns points or 0 points.
- 16. "Vital records" has the same meaning as in A.R.S. § 36-301.
- 17. 42. "Work disability" means a physical or mental condition that:
  - a. Has lasted for 6 or more at least six months,
  - b. Limits an individual's choice of jobs or makes prevents an individual unable to work for 35 or more from working for more than 34 hours per week, and
  - c. Is not a temporary health problem such as a broken bone that is expected to heal normally.

#### **R9-24-202.** Arizona Medically Underserved Area Designation

The Department shall designate as Arizona medically underserved areas:

- 1. those The primary care areas or parts of primary care areas designated as HPSAs primary care HPSAs by the Secretary of the United States U.S. Department of Health and Human Services, and
- 2. those The primary care areas identified designated as medically underserved by the primary care index described in A.A.C. the Department under R9-24-203 and Table 1.

# R9-24-203. Primary Care Index

- **A.** Using the criteria in subsection (B), the Every 12 months, the Department shall generate prepare, according to this Section, a primary care index to designate for designating primary care areas determined under R9-24-204 as Arizona medically underserved areas.
  - 1. The For each primary care area determined under R9-24-204, the Department shall calculate the value for each criterion as described in subsection (B).
    - a. After calculating the value for each criterion in subsection (B), the Department shall determine the points to be assigned assign points to each value using according to Table 1.

- b. The total score for each A primary care area area's score is the sum of:
  - i. The the points that the primary care area received by the primary care area for each criterion under subsections (B)(1) through (B)(11), in subsection (B).
  - ii. The supplementary criteria score under subsection (B)(12), and
  - iii. The sole provider or no provider score under subsection (B)(13).
- 2. The Department shall designate as Arizona medically underserved those:
  - a. The primary care areas that, according to subsection (B) and Table 1, score within the top 25% 25 percent on the primary care index or that have point totals greater than or equal to 55 obtain more than 55 points, whichever results in the designation of more Arizona medically underserved areas: and
  - b. The primary care areas or parts of primary care areas with the designation described in R9-24-202(1).
- **B.** The For each primary care area determined by the Department under R9-24-204, the primary care index shall include a score for each of the following criteria for each primary care area:
  - 1. Population-to-primary-care-provider ratio, determined by dividing the population of the primary care area by the number of primary care providers in the primary care area.
    - a. using Using primary care provider data from the Board of Arizona Medical Examiners Board, the Board of Osteopathic Examiners in Medicine and Surgery, the Arizona State Board of Nursing, and the Joint Arizona Regulatory Board on the Regulation of Physician Assistants; and
    - <u>b.</u> counting 1 Counting a full-time physician as 1.0 and 1, a full-time physician assistant or as 0.8, and a full-time registered nurse practitioner as  $\frac{.8}{0.8}$ ;
  - 2. Travel distance to the nearest primary care provider, determined by:
    - a. estimating Estimating the distance in miles:
      - <u>i.</u> <u>from From</u> the center of the most densely populated area in the primary care area <u>determined from the most</u> recent Population Estimates for Arizona's Counties, Incorporated Places and Balance of County; and
      - ii. to To the nearest primary care provider determined from the data described in subsection (B)(1)(a); and
    - b. by Using the most direct street route;
  - 3. Composite transportation score, determined by:
    - a. Compiling data on the following 6 six indicators using from the most recent decennial census published by the United States Census Bureau:
      - Percentage of population with annual calendar year income less than 100% 100 percent of the poverty level threshold;
      - ii. Percentage of population older than age 65 years of age;
      - iii. Percentage of population younger than age 14 years of age;
      - iv. Percentage of population that has with a work disability, mobility limitation, or self-care limitation;
      - v. Percentage of population without a motor vehicle; and
      - vi. The noncommercial-vehicle-to-population motor-vehicle-to-population ratio;
    - b. Calculating the statewide average value for each of the  $\frac{6}{5}$  six indicators in subsection (B)(3)(a);
    - c. Dividing the value of each indicator for each primary care area by the statewide average value for that indicator;
    - d. Multiplying the figure calculated under subsection (B)(3)(c) for each indicator by 100; and
    - e. Averaging the 6 six indicator values obtained under subsection (B)(3)(d) for each primary care area;
  - 4. Percentage of population with annual calendar year income less than 200% of the poverty level, as reported in threshold, from data in the most recent decennial census published by the United States Census Bureau;
  - 5. Percentage of population with annual income between 100% and 200% of the poverty level, as reported in threshold, from data in the most recent decennial census published by the United States Census Bureau;
  - 6. Percentage of uninsured births, determined from Office of Vital Records Department birth records reporting payment source as "self-pay" or "unknown;"
  - 7. Ambulatory care sensitive condition hospital admissions;
    - <u>a.</u> <u>based Based</u> on the number of hospital admissions for ambulatory care sensitive conditions per 1000 resident individuals <u>living in the primary care area aged who are under age</u> 65 years or younger, and
    - <u>b.</u> <u>determined Determined</u> from <u>hospital discharge record</u> data <u>on hospital discharge reporting for inpatients under 9</u> <u>A.A.C. 11, Article 4</u> provided by the <u>Department Bureau of Public Health Statistics</u>;
  - 8. Percentage of low-weight births, determined from data provided by the Office of Vital Records Department;
  - 9. Sum From data provided by the Department, the sum of the following, determined from data provided by the Office of Vital Records percentage of births for which the mothers reported:
    - a. Percentage of births for which the mothers reported having no No prenatal care,
    - b. Percentage of births for which the mothers reported commencing prenatal Prenatal care that began in the 2nd second or 3rd third trimester, and
    - c. Percentage of births for which the mothers reported having 4 Four or fewer prenatal care visits;
  - 10. Percentage of deaths at ages younger than the birth life expectancy, determined from the birth life expectancy most recent U.S. life expectancy data and data provided by the Office of Vital Records Department;

- 11. Number of infant mortalities per 1000 live births, determined from data provided by the Office of Vital Records Department;
- 12. Supplementary criteria score, determined by assigning 2 points for each based on the presence or absence in a primary care area of the following indicators that exists in the primary care area:
  - a. Percentage of minority population greater than the statewide average for all counties, determined from data in the most recent decennial census published by the United States Census Bureau;
  - b. Percentage of elderly population greater than the statewide average for all counties, determined from data in the most recent Population Estimates for Arizona's Counties, and Incorporated Places and Balance of County published by the Arizona Department of Economic Security and from data in the most recent decennial census published by the United States Census Bureau; and
  - c. Average annual unemployment rate greater than the average annual statewide rate, determined from data in the most recent-annual report issued Arizona Unemployment Statistics Program Special Unemployment Report, prepared by the Arizona Department of Economic Security; Research Administration, in cooperation with the U.S. Department of Labor, Bureau of Labor Statistics, and available at http://www.workforce.az.gov; and
- 13. Sole provider or no provider score;
  - a. determined by assigning 5 points if the Based on whether a primary care area has only 1.0 or less than 1.0 primary care provider; and
  - <u>b.</u> counting 1 Counting a full-time physician as 1.0 and 1, a full-time physician assistant or as 0.8, and a full-time registered nurses .8 nurse as 0.8.
- C. The Department shall generate a primary care index every 12 months to determine Arizona medically underserved area designations. The According to subsections (A) and (B) and Table 1, the Department shall:
  - 1. withdraw Withdraw an Arizona medically underserved area designation,
  - 2. continue Continue an Arizona medically underserved area designation, or
  - 3. designate Designate a new Arizona medically underserved area based on the criteria in subsections (A) and (B).
- <u>D.</u> The Department shall publish and keep on file a A list of current Arizona medically underserved areas is available in the Department's annual Arizona Medically Underserved Areas (AzMUA) Report at http://www.azdhs.gov/hsd/.

#### Table 1. Primary Care Index Scoring

CRITERIA	VALUE RANGE	POINTS
Population-to-primary-care-provider	≤ 2000:1	0
ratio	2001:1 to 2500:1	2
	2501:1 to 3000:1	4
	3001:1 to 3500:1	6
	3501:1 to 4000:1	8
	> 4000:1 or no provider	10
Travel distance to nearest primary care	≤ 15.0 miles	0
provider	15.1-25.0 miles	2
	25.1-35.0 miles	4
	35.1-45.0 miles	6
	45.1-55.0 miles	8
	> 55.0 miles	10
Composite transportation score	50th 51st highest score and below	0
	41st-50th highest scores	2
	31st-40th highest scores	4
	21st-30th highest scores	6
	11th-20th highest scores	8
	10 highest scores	10
Percentage of population with annual	≤ 15.0%	0
income less than 200% of poverty level	15.1-25.0%	2
threshold	25.1-35.0%	4
	35.1-45.0%	6
	45.1-55.0%	8
	>55.0%	10

Percentage of population with annual income between 100% and 200% of poverty level threshold	\( \le 10.0\% \) \( 10.1-15.0\% \) \( 15.1-20.0\% \) \( 20.1-25.0\% \) \( 25.1-30.0\% \) \( > 30.0\% \)	0 2 4 6 8 10
Percentage of uninsured births	<pre> ≤ 6.0% 6.1-10.0% 10.1-14.0% 14.1-18.0% 18.1-22.0% &gt;22.0%</pre>	0 2 4 6 8 10
Ambulatory care sensitive condition hospital admissions	≤ 8.0 8.1-12.0 12.1-16.0 16.1-20.0 20.1-24.0 > 24.0	0 2 4 6 8 10
Percentage of low-weight births	<pre> ≤ 6.0% 6.1-8.0% 8.1-10.0% 10.1-12.0% 12.1-14.0% &gt;14.0%</pre>	0 2 4 6 8 10
Sum of the following percentage of births with:  a. Percentage of births with no No prenatal care, b. Percentage of births with prenatal Prenatal care begun in 2nd second or 3rd third trimester, and c. Percentage of births with prenatal Prenatal care visits ≤ 4	<pre> ≤ 15.0% 15.1-25.0% 25.1-35.0% 35.1-45.0% 45.1-55.0% &gt;55.0%</pre>	0 2 4 6 8 10
Percentage of deaths at ages younger than birth life expectancy	\$\leq 40.0\%\$ 40.1-50.0\%\$ 50.1-60.0\%\$ 60.1-70.0\%\$ 70.1-80.0\%\$ >80.0\%\$	0 2 4 6 8 10
Number of infant mortalities per 1000 live births	≤ 4.0 4.1-6.0 6.1-8.0 8.1-10.0 10.1-12.0 >12.0	0 2 4 6 8 10
Supplementary criteria score	1 Criterion 2 Criteria 3 Criteria	2 4 6
Sole provider or no provider score	primary Primary care provider ≤ 1.0 primary Primary care provider providers > 1.0	5
Key to Symbols ≤ represents "less than or equal to" > represents "more than"		

### **R9-24-204.** Primary Care Area Designation Boundaries Determination

- **A.** The Department shall designate determine the boundaries of primary care areas within the for the entire state. A primary care area's boundaries shall that meet the following eriteria requirements:
  - 1. Each primary care The geographic area within the boundaries is not smaller than the smallest unit of census geography used on corresponds to or is larger than a census block identified for the geographic area in the most recent decennial census published by the United States Census Bureau; and
  - 2. The boundaries of each primary care area The boundaries are consistent with the population's primary care services utilization patterns of its population for primary care services, determined by considering:
    - a. The geographic area's:
      - a. i. Topography;,
      - b. ii. Social, and cultural relationships,
      - iii. and geopolitical Political subdivision boundaries; and
      - e. iv. Travel patterns for the geographic area; and
    - d. b. Data about the type, amount, and location of primary care services used by the geographic area's population, from local planning personnel, government officials, health organizations, primary care providers, and residents of the geographic area about the type, amount, and location of primary care services used by the population.
- **B.** The In addition to the requirements for primary care area boundaries in subsection (A), the Department shall consider the following additional factors in determining the boundaries of each primary care area:
  - 1. Boundaries of Indian reservations reservation boundaries, and
  - 2. Boundaries of HPSAs Primary care HPSA boundaries.
- C. Local A primary care area's local planning personnel, government officials, health organizations, primary care providers, or residents of a primary care area may submit to the Department a request to change the boundaries of a primary care area boundary change request.
  - 1. The request A person requesting a boundary change shall:
    - a. be made Make the request in writing and,
    - b. shall include documentation to support supporting the boundary change., and
    - <u>c.</u> The request shall be submitted Submit the request by October 1 to be considered for inclusion in the next calendar year's Arizona medically underserved area designation process for the following calendar year.
  - 2. The time-frames for the request for change of boundaries are in A.A.C. R9-24-102. Department shall review a primary care area boundary change request according to the time-frames in R9-24-205.

### **R9-24-205.** Repealed <u>Time-frames</u>

- A. The overall time-frame described in A.R.S. § 41-1072 for a primary care area boundary change request under R9-24-204(C) is 90 days.
  - 1. A person requesting a boundary change and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame.
  - 2. An extension of the substantive review time-frame and the overall time-frame may not exceed 25 percent of the overall time-frame.
- **B.** The administrative completeness review time-frame described in A.R.S. § 41-1072 for a primary care area boundary change request under R9-24-204(C) is 30 days and begins on the date the Department receives a boundary change request.
  - 1. Within the administrative completeness review time-frame, the Department shall mail a notice of administrative completeness or a notice of deficiencies to the person requesting a boundary change.
    - a. A notice of deficiencies shall list each deficiency and the information or documents needed to complete the boundary change request.
    - b. A notice of deficiencies suspends the administrative completeness review time-frame and the overall time-frame from the date the Department mails the notice until the date the Department receives the missing information or documents.
    - c. If the person requesting a boundary change does not submit to the Department all the information and documents listed in the notice of deficiencies within 60 days after the date the Department mails the notice of deficiencies, the Department considers the boundary change request withdrawn.
  - 2. If the Department approves a boundary change request during the administrative completeness review time-frame, the Department does not issue a separate written notice of administrative completeness.
- C. The substantive review time-frame described in A.R.S. § 41-1072 for a primary care area boundary change request under R9-24-204(C) is 60 days and begins on the date the Department mails the notice of administrative completeness.
  - 1. Within the substantive review time-frame, the Department shall mail written notification of approval or denial of the boundary change request to the person requesting a boundary change.
  - 2. During the substantive review time-frame:
    - a. The Department may make one comprehensive written request for additional information; and
    - b. If the Department and the person requesting a boundary change agree in writing to allow one or more supple-

- mental requests for information, the Department may make the number of supplemental requests for information agreed to.
- 3. A comprehensive written request for additional information or a supplemental request for information suspends the substantive review time-frame and the overall time-frame from the date the Department mails the request until the date the Department receives all the information and documents requested.
- 4. If the person requesting a boundary change does not submit to the Department all the information and documents listed in a comprehensive written request for additional information or a supplemental request for information within 60 days after the date the Department mails the request, the Department shall deny the boundary change request.
- **D.** The Department shall approve a primary care area boundary change request under R9-24-204(C) unless:
  - 1. The requested boundaries do not meet the requirements in R9-24-204(A).
  - 2. The considerations required in R9-24-204(B) outweigh the information and documents submitted with the boundary change request, or
  - 3. The boundary change request comes within subsection (B)(1)(c) or (C)(4).

#### ARTICLE 3. COORDINATING MEDICAL PROVIDERS

#### R9-24-301. Definitions

In addition to the definitions in A.R.S. § 36-2351 and 9 A.A.C. 24, Article 2, the following definitions apply in this Article, unless otherwise specified:

- 1. "CMP" means coordinating medical provider, as defined in A.R.S. § 36-2351.
- 2. "Continuing medical education" means instruction that meets the requirements in:
  - a. A.A.C. R4-16-101 for a physician licensed under A.R.S. Title 32, Chapter 13;
  - b. A.A.C. R4-17-205 for a physician assistant licensed under A.R.S. Title 32, Chapter 25; and
  - c. A.R.S. § 32-1824, A.A.C. 4-22-109, and A.A.C. 4-22-110 for a physician licensed under A.R.S. Title 32, Chapter 17.
- 3. "Continuing nursing education" means instruction that:
  - a. Is required by A.A.C. R4-19-507 for authorization from the Arizona State Board of Nursing for a registered nurse practitioner to prescribe and dispense medication;
  - b. Meets requirements established by a nurse credentialing organization, such as the American Nurses Credentialing Center; or
  - c. Provides training related to the performance of a nurse's job duties.
- 4. "Drug prescription services" means the provision of medication that requires an order by medical personnel authorized by law to order the medication.
- 5. "Durable medical equipment" means an item that:
  - a. Can withstand repeated use,
  - b. Is designed to serve a medical purpose, and
  - c. Generally is not useful to an individual in the absence of a medical condition, illness, or injury.
- 6. "Governing authority" has the same meaning as in A.R.S. § 36-401.
- 7. "Independent decision" means a registered nurse practitioner's action without a physician's order, including:
  - a. Prescribing or dispensing medication,
  - b. Ordering or performing a test or procedure, or
  - c. Referring an individual to a physician.
- 2. "Medical clinic" has the same meaning as in A.R.S. § 36 2351.
- 8. "Medical direction" means guidance, advice, or consultation provided by a CMP to a registered nurse practitioner.
- 3. 9. "Medical personnel" means a medical clinic's physicians, physician assistants, registered nurse practitioners, and nurses-of a medical clinic.
- 4. 10. "Nurse" means an individual licensed as a graduate, professional, or registered nurse or as a practical nurse under A.R.S. Title 32, Chapter 15.
- 11. "Order" means a written directive.
- 12. "Practice requirements" means the standards for physicians established in:
  - a. A.R.S. Title 32, Chapter 13 and 4 A.A.C. 16; or
  - b. A.R.S. Title 32, Chapter 17 and 4 A.A.C. 22.
- 13. "Referral source" means a person who sends an individual to a third person for medical services.
- 14. "Social services" means assistance, other than medical services, provided to maintain or improve an individual's physical, mental, and social participation capabilities.
- 15. "Supervision" has the same meaning as in A.R.S. § 32-2501.
- 5. 16. "Support services" means drug prescription services, social services, and provision of durable medical equipment.
- 17. "Work schedule coverage" means a medical clinic's system for filling gaps in the presence of medical personnel.

# **Notices of Proposed Rulemaking**

18. "Written protocol" means an agreement that identifies and is signed by a CMP and a registered nurse practitioner or a physician assistant.

#### **R9-24-302.** Functions

- A. A CMP shall:
  - 1. Be involved <u>Participate</u> in planning for the delivery of medical services <u>and support services</u> within the Arizona medically underserved area <u>that includes ways to increase access to medical services and support services for the Arizona medically underserved area's residents;</u>
  - 2. Ensure access to medical and support services, either directly or by referral, for the residents of the Arizona medically underserved area;
  - 3.2. Develop written protocols that:
    - a. identify areas in which Describe the manner and frequency that a registered nurse practitioners and practitioner or a physician assistants under the CMP's supervision may use independent judgment assistant at a medical clinic will communicate with the CMP, in addition to the face-to-face meeting required in subsection (A)(5);
    - b. Specify the criteria used by a registered nurse practitioner at the medical clinic in making an independent decision to refer an individual to a physician; and
    - c. Specify procedures to be followed by a physician assistant at the medical clinic when the CMP's supervision of the physician assistant is by a means other than physical presence;
  - 4.3. Have final approval in Approve or disapprove the selection of registered nurse practitioners and physician assistants working under the CMP's supervision who will work at the medical clinic;
  - 5.4. Have authority over and responsibility for the Provide:
    - <u>a.</u> <u>medical Medical</u> direction <u>of all to the</u> registered nurse practitioners <u>and physician assistants under the CMP's supervision;</u> at the medical clinic, and
    - b. Supervision to the physician assistants at the medical clinic;
  - 6.5. Evaluate At least weekly, conduct a face-to face meeting with each registered nurse practitioner and each physician assistant at the medical clinic to evaluate the medical eare services provided by the registered nurse practitioners and practitioner or physician assistants assistant under the CMP's supervision through a face-to-face contact at least once per week;
  - 7-6. For continuing medical education or continuing nursing education of a medical clinic's medical personnel:
    - a. Recommend specific areas of medical education instruction, including instruction in referral sources; and
    - <u>b.</u> <u>Develop a written plan for work</u> schedule coverage to <u>allow for the accommodate</u> continuing medical education <u>of medical personnel at the medical elinic or continuing nursing education</u>; and
  - 8. 7. Meet at At least annually, meet with the organization that owns and operates the medical elinic clinic's governing authority to evaluate the medical clinic's program and the medical care provided by the medical clinic's medical personnel of the medical elinic.
- **B.** These The requirements in subsection (A) do not replace other requirements of practice the practice requirements applicable to a CMP.

#### NOTICE OF PROPOSED RULEMAKING

#### TITLE 9. HEALTH SERVICES

# CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

[R05-359]

#### **PREAMBLE**

1. Sections Affected	Rulemaking Action
Article 7	New Article
R9-25-701	New Section
R9-25-702	New Section
R9-25-703	New Section
R9-25-704	New Section
R9-25-705	New Section
R9-25-706	New Section
R9-25-707	New Section

R9-25-708 R9-25-709 R9-25-710 R9-25-711 R9-25-712 R9-25-713 R9-25-714 R9-25-715 R9-25-716 R9-25-717 R9-25-718 Article 8 R9-25-801 R9-25-802 R9-25-803 R9-25-804 R9-25-805 R9-25-807 Table 1 R9-25-1201 Table 1	New Section New Table Amend Amend
Table 1	Amena

# 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statutes: A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); 36-2212; 36-2213; 36-2214; 36-2215; 36-2217; 36-2232(A)(11); 36-2234(L); 36-2240(4); 41-1072 through 41-1079; 41-1092.03; and 41-1092.11

# 3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 4196, October 15, 2004

### 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Ed Armijo, Ambulance and Regional Services Section Chief

Address: Arizona Department of Health Services

Bureau of Emergency Medical Services

150 N. 18th Ave., Suite 540

Phoenix, AZ 85007

Telephone: (602) 364-3165 Fax: (602) 364-3568

E-mail: armijoe@azdhs.gov

Or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services Office of Administrative Rules 1740 W. Adams, Suite 202

Phoenix, AZ 85007

Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: phillik@azdhs.gov

# 5. An explanation of the rule, including the agency's reasons for initiating the rule:

### a. Regulatory History

The statutes authorizing the Arizona Department of Health Services (ADHS) to regulate the area of emergency medical services (EMS), including ambulances and ambulance services, are included in A.R.S. Title 9, Chapter 21.1, Articles 1 and 2. In 1982, with the express intent of regulating ambulances, ambulance services, and ambulance equipment only with respect to essential public health and safety matters, the Arizona Legislature adopted legislation requiring ADHS to license ambulance services and register ambulances. In September 1982, ADHS adopted rules in

# **Notices of Proposed Rulemaking**

9 A.A.C. 13, Articles 10-12 to require ground, air, and water ambulance services to be licensed and to require ground, air, and water ambulances to be registered.

In November 1982, the Arizona Constitution was amended to include Article XXVII, which granted the Arizona Legislature express authority to provide for the regulation of ambulances and ambulance services in Arizona in all matters relating to services provided, routes served, response times, and charges. In 1983, with the express intent of implementing Article XXVII of the Arizona Constitution, the Arizona Legislature adopted legislation requiring ADHS to regulate ambulance service rates, operating and response times, service areas, accounting, and reporting through requiring each ambulance service to obtain a certificate of necessity to operate in Arizona. In November 1983, ADHS adopted rules for ambulance service certificates of necessity in 9 A.A.C. 13, Article 14.

In 1987, the Arizona Attorney General (AG) determined that the Federal Airline Deregulation Act of 1978 preempted ADHS from enforcing economic regulation of air ambulance services under the certificate-of-necessity statutes and rules, although it did not preempt ADHS's authority to regulate air ambulance services with regard to essential public health and safety matters. Specifically, 49 U.S.C. § 41713 (then 49 U.S.C. § 1305) preempts a state from "enact[ing] or enforc[ing] a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier that may provide air transportation under [49 U.S.C. §§ 41101 *et seq.*]." As a result of the 1987 determination by the AG, ADHS ceased its enforcement of the certificate-of-necessity statutes and rules as related to air ambulance services, although ADHS continued to enforce the statutes and rules related to air ambulance service licensure and air ambulance registration (and to enforce the certificate-of-necessity statutes and rules as related to ground ambulance services).

In 1993, the Arizona Legislature repealed ADHS's statutory authority to license ambulance services, thereby nullifying the ambulance service licensure rules in 9 A.A.C. 13, Article 10. ADHS ceased its enforcement of the ambulance service licensure rules, but continued to enforce the statutes and rules for ambulance registration.

In 1995, the Arizona Legislature granted ADHS statutory authority to license **air** ambulance services (but not ground or water ambulance services) by adopting A.R.S. §§ 36-2213 through 36-2215. These statutes have not yet been implemented by ADHS. Because the air ambulance service licensure rules in 9 A.A.C. 13 were outdated and inconsistent with the requirements enacted in 1995, ADHS did not revive the air ambulance service licensure program using those rules. As a result, ADHS has not licensed air ambulance services since 1993, although ADHS has continued to require air ambulance registration. The only requirement from the air ambulance licensure statutes and rules that ADHS currently enforces is the A.R.S. § 36-2215 and A.A.C. R9-13-1001(B)(2) requirement for an air ambulance service to have liability and malpractice insurance coverage in the amount of at least \$1 million. ADHS does currently enforce most of the provisions in 9 A.A.C. 13, Articles 11 and 12 related to air ambulance registration.

# b. Statutory Authority for Air Ambulance Service Licensure

A.R.S. § 36-2213 requires ADHS to adopt rules to establish minimum standards for the operation of air ambulance services that are necessary to assure the public health and safety, which shall provide for ADHS to:

- 1. Establish standards and requirements relating to at least:
  - a. Medical control plans that shall conform to the standards adopted pursuant to A.R.S. § 36-2204(9);
  - b. Qualifications of the medical director of an air ambulance service; and
  - c. Operation of only those air ambulances registered pursuant to A.R.S. § 36-2212 and licensed pursuant to A.R.S. Title 28, Chapter 25;
- 2. Establish response times and operation times to assure that the health and safety needs of the public are met;
- 3. Establish standards for emergency medical dispatch training, including prearrival instruction;
- 4. Require the filing of run log information;
- 5. Issue, transfer, suspend, or revoke air ambulance service licenses under terms and conditions consistent with A.R.S. Title 36, Chapter 21.1 and consistent for all ambulance services;
- 6. Investigate the operation of an air ambulance service, including a person operating an ambulance that has not been issued a certificate of registration, and conduct onsite investigations of facilities, communications equipment, vehicles, procedures, materials, and equipment;
- 7. Prescribe the terms of the air ambulance service license; and
- 8. Prescribe the criteria for the air ambulance service license inspection process and for determining an air ambulance service's compliance with licensure requirements (ADHS is required to accept proof that an air ambulance service is accredited by the Commission on Accreditation of Air Medical Services (now known as the Commission on Accreditation of Medical Transport Services (CAMTS)) in lieu of all licensing inspections if ADHS receives a copy of the air ambulance service's accreditation report).

A.R.S. § 36-2214 prohibits a person from operating an air ambulance service in Arizona unless the air ambulance service is licensed and complies with A.R.S. Title 36, Chapter 21.1, Article 1 and the rules adopted under the Article and requires ADHS to conduct an inspection before issuing an initial or renewal license, unless the license is submitted as a result of a change in ownership, in which case ADHS may determine that an inspection is not needed.

A.R.S. § 36-2215 prohibits ADHS from issuing an air ambulance service license unless the applicant or licensee provides ADHS proof of malpractice and liability insurance in an amount determined by ADHS in rule.

### c. Statutory Authority for Air Ambulance Registration

A.R.S. § 36-2202(Å)(5) requires ADHS to adopt reasonable medical equipment, supply, staffing, and safety standards; criteria; and procedures for issuance of a certificate of registration to operate an ambulance. "Ambulance" is defined in A.R.S. § 36-2201(3):

"Ambulance" means any publicly or privately owned surface, water or air vehicle, including a helicopter, that contains a stretcher and necessary medical equipment and supplies pursuant to section 36-2202 and that is especially designed and constructed or modified and equipped to be used, maintained or operated primarily for the transportation of individuals who are sick, injured or wounded or who require medical monitoring or aid. Ambulance does not include a surface vehicle that is owned and operated by a private sole proprietor, partnership, private corporation or municipal corporation for the emergency transportation and in-transit care of its employees or a vehicle that is operated to accommodate an incapacitated or disabled person who does not require medical monitoring, care or treatment during transport and that is not advertised as having medical equipment and supplies or ambulance attendants.

A.R.S. § 36-2212 prohibits a person from operating an ambulance in Arizona unless the ambulance has a certificate of registration and complies with A.R.S. Title 36, Chapter 21.1, Article 1 and the rules, standards, and criteria adopted pursuant to the Article. A.R.S. § 36-2212 further establishes that a certificate of registration is not transferable and is generally valid for one year and requires ADHS to charge a fee of not more than \$50 for initial or renewal registration.

Although most of A.R.S. Title 36, Chapter 21.1, Article 2 is inapplicable to air ambulance services because it applies specifically to certificates of necessity, which are no longer required for air ambulance services as a result of federal preemption, several provisions pertain specifically to certificates of registration and can be applied to air ambulances without running afoul of the federal preemption:

- 1. A.R.S. § 36-2232(A)(11) requires ADHS to inspect each ambulance registered under A.R.S. § 36-2212 at least every 12 months to ensure that the ambulance is operational and safe and that all required medical equipment is operational and provides that, upon request from a provider and at the provider's expense, an inspection may be performed by a facility approved by ADHS;
- 2. A.R.S. § 36-2234(L) authorizes ADHS, in case of emergency, to immediately suspend a certificate of registration if the director determines that a potential threat to the public health and safety exists and establishes requirements for a post-suspension hearing; and
- 3. A.R.S. § 36-2240(4) requires ADHS to charge an annual regulatory fee of not more than \$200 for each ambulance issued a certificate of registration pursuant to A.R.S. § 36-2212, to be collected at the same time as the certificate of registration fee imposed by A.R.S. § 36-2212.

#### d. Statutory Exemptions

A.R.S. § 36-2217(A) enumerates specific exemptions to A.R.S. Title 9, Chapter 21.1. In the context of air ambulance regulation, the relevant exemptions are for the following:

- 1. Vehicles used for the emergency transportation of persons injured at an industrial site;
- 2. Persons engaged in and vehicles used for air transportation of sick or injured people in a noncritical or nonemergency situation as determined by a physician;
- 3. Medical evacuation equipment used and owned by the Arizona Department of Public Safety in air evacuation and including fixed-wing aircraft and helicopters;
- Vehicles provided or contracted for emergency medical services by a political subdivision if these vehicles are primarily used to provide on-the-scene stabilization of sick, injured, wounded, incapacitated, or helpless persons; and
- 5. Ambulances from other states that are:
  - a. Responding to a major catastrophe or emergency in Arizona because there are insufficient registered ambulances in Arizona to respond in that situation, or
  - b. Operating either from a location outside of Arizona to transport a patient to a location within Arizona or operating from a location outside of Arizona and crossing through Arizona to transport a patient to a location outside of Arizona.

A.R.S. § 36-2217(B) further provides that, except as provided in (5)(a) above, an ambulance from another state shall not pick up a patient in Arizona and transport that patient to another location in Arizona unless the ambulance is registered under A.R.S. Title 36, Chapter 21.1.

#### e. This Rulemaking

In this rulemaking, ADHS creates new rules, in 9 A.A.C. 25, Articles 7 and 8, for air ambulance service licensure and air ambulance registration and revises the time-frame provisions in 9 A.A.C. 25, Article 12 to add the processes for air ambulance service licensure. The new rules are consistent with ADHS's current statutory authority, with the limitations imposed by federal preemption, and with current rulemaking format and style requirements.

# **Notices of Proposed Rulemaking**

To create these rules, ADHS invited each air ambulance service operating in Arizona; the Arizona Department of Public Safety; ground ambulance services from each EMS region representing urban, rural, and wilderness areas; first response agencies representing urban and rural fire/EMS and law enforcement; and the Arizona Hospital and Health-care Association to participate in an Air Ambulance Rulemaking Task Force (Task Force). ADHS formed the Task Force so that interested persons within the EMS community would be able to share their expertise and provide ADHS with recommendations for the rules. Not all of the invitees participated in the Task Force, but ADHS kept all of the invitees informed through e-mail notifications regarding the substance of the draft rules and the progress of the rule-making. ADHS also allowed other interested persons to participate in the Task Force meetings and included them in the e-mail notifications. The Task Force held four meetings and reviewed five different revisions of draft rules from December 2004 through March 2005. ADHS then solicited public comment on a sixth revision of the draft rules in April-May 2005. After reviewing the comments received and upon further internal review, ADHS asked the Task Force to review a seventh revision of the draft rules in June 2005 and an eighth revision of the draft rules in July 2005. After reviewing the Task Force members' comments, ADHS made final revisions to the draft rules and created this Notice of Proposed Rulemaking, which ADHS believes to be consistent with the consensus recommendations of the participating Task Force members.

#### f. Concurrent Companion Rulemaking

In a concurrent companion rulemaking, ADHS is repealing the rules in 9 A.A.C. 13, Articles 10-12. The rules will no longer be needed when the rules for air ambulance service licensure and air ambulance registration are adopted in 9 A.A.C. 25.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

ADHS did not review or evaluate any study.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

This summary describes the major economic impacts that are expected to result from this rulemaking. As used in this summary, "minimal" means less than \$1,000; "moderate" means \$1,000 to \$9,999; "substantial" means \$10,000 or more; and "significant" means meaningful or important, but not readily subject to quantification. For the sake of brevity and because an air ambulance service (AAS) license is a prerequisite to obtaining a certificate of registration, ADHS uses the term "AAS" instead of "certificate holder" in this summary to describe the effects of the air ambulance registration rules on certificate holders (who are all AASs as well).

There are currently 13 private AASs operating in Arizona, with a total of 91 registered air ambulances, 38 fixed wing and 53 rotor wing. The 13 private AASs operate between 1 and 20 air ambulances each, with 4 operating only fixed-wing air ambulances and 3 operating only rotor-wing air ambulances. Of the 13 AASs, 7 currently hold CAMTS accreditation. ADHS believes that as many as 3 of the 13 AASs may be small businesses as defined in A.R.S. § 41-1001.

The Arizona Department of Public Safety also owns and operates air ambulances, but is not subject to these rules because of the exemption in A.R.S. § 36-2217(A)(3).

The rules in Article 7 establish the standards and processes for air ambulance service licensing. A.R.S. § 36-2214 prohibits a person from operating an AAS in Arizona without having a valid AAS license. Thus, although ADHS has not been enforcing the requirement for an AAS license, the requirement for AAS licensure actually results from statute rather than from the new rules. ADHS recognizes, however, that implementing the statute anew will have a significant impact on AASs, which are accustomed to operating without regulation of the AAS itself and may need to adjust operations to comply with the new requirements imposed by rule. Implementing the statute will also result in a substantial cost to ADHS, from the time and expenses incurred in planning for program extension; creating new application forms, a new inspection tool, and an internal operating procedure; establishing a new database; tracking time-frames for licensure; training staff to enforce the statutes and rules; and operating and managing the licensure program. ADHS believes that ADHS, patients, patient loved ones, and AASs will receive a significant benefit from the new scheme for AAS licensure because licensure will help to ensure the health and safety of patients and should also enhance consistency in quality of care and thus the reputations of all AASs.

R9-25-703 establishes eligibility requirements for an AAS license. ADHS believes that the only eligibility requirement that may have an impact on AASs is the requirement to have minimum liability insurance coverage of \$1 million for injuries/death to one person in one incident/accident; \$3 million for injuries/death to more than one person in one incident/accident; and \$500,000 for property damage from one incident/accident. Currently, ADHS is requiring AASs to submit proof of liability and malpractice insurance with minimum coverage of \$1 million for liability and \$1 million for malpractice. The increased liability coverage requirements in the new rule may result in a minimal-to-moderate cost to an AAS, depending on the insurance coverage currently held and the related change in premium. Patients and patient loved ones may receive a substantial benefit from this increase in liability insurance coverage

because it helps to ensure that monetary recovery is available if a patient is harmed by an AAS. The general public may also receive a substantial benefit from the increased liability insurance coverage because specific coverage is required for property damage.

R9-25-704 establishes the information and documents to be submitted in an initial licensure application and requires ADHS to conduct a pre-licensure inspection if an AAS does not hold CAMTS accreditation. Because A.R.S. § 36-2214 requires ADHS to conduct a pre-licensure inspection unless an AAS holds CAMTS accreditation, the inspection requirement really results from statute rather than from this rule. However, ADHS's implementation of this statutory requirement will result in a moderate annual cost to ADHS from the time and travel-related expenses incurred and in a minimal impact to each AAS inspected from the time spent participating in an inspection. ADHS believes that ADHS, patients, and patient loved ones will receive a significant benefit from ADHS's performing pre-licensure inspections because the inspections will help to ensure patient health and safety.

R9-25-708 provides that ADHS may inspect an AAS as often as necessary to determine compliance and that ADHS shall conduct an investigation, which may include an inspection, in response to written or verbal information alleging a violation. This rule may result in a moderate cost to an AAS from the time spent participating in an inspection or investigation. In addition, ADHS may incur moderate-to-substantial costs from performing interim inspections to determine compliance and from conducting investigations, which may include inspections, whenever allegations of noncompliance are received. The costs incurred by ADHS as a result of these requirements will depend upon the number of allegations received, the extensiveness of each necessary investigation, and ADHS's determinations regarding the necessity of an inspection during each investigation. ADHS believes that this rule should result in a significant benefit to ADHS, patients, and patient loved ones because ADHS's inspections and investigations should help to ensure patient health and safety.

R9-25-711 requires an AAS generally to staff missions with medical teams of at least two individuals with at least the following qualifications:

- For a critical care (CC) mission, at least:
  - · A physician or registered nurse, and
  - An EMT-Paramedic (EMT-P) or licensed respiratory care practitioner;
- For an advanced life support (ALS) mission, at least:
  - An EMT-P, and
  - Another EMT-P or a licensed respiratory care practitioner; and
- For a basic life support (BLS) mission, at least two EMT-Basics (EMT-Bs).

ADHS believes that these minimum staffing requirements are consistent with the industry standard and should not result in a cost to any AAS. If an AAS is not currently staffing missions with medical teams that meet these minimum staffing requirements, however, the requirements will result in a substantial cost to the AAS. ADHS believes that establishing these minimum staffing requirements may result in a significant benefit to ADHS and to patients and patient loved ones because it helps to ensure that an appropriate standard of care is met for each type of mission and thus may enhance patient health. These standards also may result in a substantial benefit to each individual hired by an AAS to ensure that the AAS has the minimum medical team required by the rules for each type of mission.

R9-25-715 requires an AAS to have a medical director who:

- Meets prescribed qualifications;
- Supervises and evaluates the quality of medical care provided by medical team members;
- Ensures the competency and current qualifications of medical team members;
- Ensures that EMT medical team members receive medical direction as required under 9 A.A.C. 25, Article 2;
- Ensures that each non-EMT medical team member receives medical guidance through written treatment protocols and on-line medical guidance provided by the medical director or a designee physician or consulting specialty physician; and
- Approves, ensures implementation of, and annually reviews treatment protocols to be followed by medical team members.

ADHS believes that having an AAS medical director who performs these functions is the industry standard, as evidenced by its inclusion in CAMTS standards and the Air Medical Physician Associations' Air Medical Physician Handbook (1999). However, ADHS believes that it is possible that some AASs' current medical directors may not meet the prescribed qualifications, which would result in a substantial cost to an AAS from having to obtain the services of a medical director who meets the prescribed qualifications and could also result in a substantial cost to each current AAS medical director who will no longer be qualified to serve as an AAS medical director after the rules take effect, although a former AAS medical director may still be able to provide medical direction for an AAS under the supervision of the medical director. ADHS believes that this requirement may result in a significant benefit to ADHS, AASs, AAS personnel members, and patients and patient loved ones because it helps to ensure that an AAS has a medical director whose knowledge and qualifications are consistent with the scope of missions offered by the AAS and that the medical director oversees all aspects of the medical care provided by the AAS, which should enhance the care provided.

# **Notices of Proposed Rulemaking**

R9-25-717 and R9-25-718 establish supplemental requirements for interfacility neonatal missions (INMs) and interfacility maternal missions (IMMs), including requirements for:

- INM and IMM medical team member proficiencies;
- AAS medical director verification of and attestation as to INM and IMM medical team member proficiencies;
- Additional equipment and supplies to be carried on INM and IMM missions; and
- On-line medical direction and on-line medical guidance to be provided by a physician who is board certified in or who has completed an accredited residency program in:
  - OB/GYN with subspecialization in maternal and fetal medicine or, for an IMM only, critical care medicine; or
  - Pediatrics with subspecialization in neonatal-perinatal medicine or, for an INM only, neonatology, pediatric critical care medicine, or pediatric intensive care.

ADHS believes that these requirements will result in no additional costs to the AASs that perform most of the INMs and IMMs in Arizona, as most of the INMs and IMMs are performed by AASs under contract with the ADHS High Risk Perinatal Program/Newborn Intensive Care Program (HRPP/NICP) Transport Program, which requires certifications that fulfill the proficiency requirements, that all of the additional equipment and supplies be carried during an INM or IMM, and that on-line medical direction or on-line medical guidance be obtained from an HRPP/NICP-contracted perinatologist or neonatologist. For AASs that are not HRPP/NICP Transport Program contractors, however, these rules could result in a substantial cost from the costs of training medical team members to fulfill the proficiencies or the potentially increased salaries that already qualified medical team members may command and the costs of purchasing the additional equipment and supplies. The rules may result in no additional costs to any AASs, however, because AASs frequently perform INMs and IMMs using sending-health-care-institution medical teams and equipment and thus would not incur any additional costs from the supplemental requirements of the rules. The requirement to obtain on-line medical direction or on-line medical guidance from a qualified specialist should result in no costs because the HRPP/NICP Transport Program contracts with neonatology and perinatology groups in Arizona to provide medical consultation regarding treatment, stabilization, and approval or coordination of neonatal and maternal transports free of charge to all callers. These rules may result in a significant benefit to ADHS, AASs, and patients and patient loved ones because they may help to ensure that an appropriate standard of care is met during INMs and IMMs, which enhances patient health.

The rules in Article 8 establish the standards and processes for air ambulance registration. These rules replace the rules in 9 A.A.C. 13, Articles 11 and 12, which are outdated and are being repealed in a concurrent companion rule-making. A.R.S. § 36-2212 prohibits a person from operating an ambulance in Arizona unless the ambulance has a certificate of registration and complies with A.R.S. Title 36, Chapter 21.1, Article 1 and the rules, standards, and criteria adopted thereunder, and ADHS has been certifying air ambulances using the rules in 9 A.A.C. 13 since their adoption in 1982.

R9-25-802 establishes the eligibility and application requirements for an initial or renewal certificate of registration for an air ambulance. ADHS believes that the only requirement in R9-25-802 that will have a meaningful impact on AASs is the requirement to submit an annual regulatory fee of \$200 with each application for air ambulance registration. This will result in a minimal-to-moderate annual cost to an AAS, depending on the number of air ambulances operated, because ADHS has not been charging the annual regulatory fee, although ADHS is required to charge an annual regulatory fee under A.R.S. § 36-2240(4). This will result in a substantial benefit to the state of Arizona and potentially to ADHS because ADHS will be depositing approximately an additional \$18,200 in fees into the General Fund each year.

R9-25-807 requires an AAS to ensure that an air ambulance meets prescribed standards for configuration and equipment, including a requirement for each fixed-wing air ambulance to have pressurization capability. This requirement could result in a substantial cost to an AAS, if the AAS desires to use a fixed-wing air ambulance without this capability. ADHS believes, however, that most, if not all, of the fixed-wing aircraft currently used as air ambulances in Arizona have pressurization capability. CAMTS expresses a strong preference for pressurized aircraft, and the ADHS air ambulance registration rules in 9 A.A.C. 13 required that a fixed-wing neonatal transport be done using a pressurized aircraft and that a fixed-wing air ambulance have a cabin with pressurization capability for patient transport under medical conditions that require pressurization, as determined by the AAS medical director under ADHS-issued guidelines. ADHS believes that this requirement may result in a significant benefit to patients and patient loved ones because it should help to ensure that patients do not suffer negative effects from the conditions inherent in flight.

R9-25-807 also requires an AAS to ensure, with one exception, that each air ambulance has the equipment and supplies required in Table 1 for each mission level for which the air ambulance is used—ALS, BLS, or CC—with some distinctions between fixed-wing and rotor-wing aircraft, and that the equipment and supplies are secured, stored, and maintained in a manner that prevents hazards to personnel and patients. This rule may result in a minimal-to-moderate cost per air ambulance to an AAS, depending upon the equipment and supplies currently carried on the AAS's air ambulances for the different mission levels. Some of the more expensive additional equipment and supply requirements include an automated external defibrillator on BLS missions and a transcutaneous cardiac pacemaker on ALS and CC missions.

This requirement may result in a significant benefit to ADHS, AASs, and patients and patient loved ones because it will help to ensure that each air ambulance has the equipment and supplies needed by the medical team members to provide an appropriate standard of care during missions, which enhances patient health.

R9-25-807 allows an AAS to perform an interfacility CC mission using an air ambulance that does not have all of the equipment and supplies required in Table 1 if:

- Care of the patient to be transported necessitates use of life-support equipment that because of its size or weight or both makes it unsafe or impossible for the air ambulance to carry all of the equipment and supplies required in Table 1 for the mission level, and
- Other prescribed requirements are met.

ADHS believes that this may result in a substantial benefit to each AAS that performs interfacility CC missions using life-support equipment such as an intra-aortic balloon pump and in a significant benefit to each patient who needs air ambulance transport using such life-support equipment and to each such patient's loved ones. Although the rule allows for an AAS to perform these interfacility CC missions without having all of the equipment and supplies otherwise required for a CC mission in Table 1, ADHS believes that the other requirements prescribed in R9-25-807(C) adequately protect public health and safety by ensuring that this exception will be used only when appropriate and that an air ambulance that is not fully equipped for another mission will not be used for another mission until it is fully equipped.

### The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Ed Armijo, Ambulance and Regional Services Section Chief Name:

Address: Arizona Department of Health Services Bureau of Emergency Medical Services

150 N. 18th Ave., Suite 540

Phoenix, AZ 85007

Telephone: (602) 364-3165 Fax: (602) 364-3568

E-mail: armijoe@azdhs.gov

Or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

Office of Administrative Rules 1740 W. Adams, Suite 202

Phoenix, AZ 85007

(602) 542-1264 Telephone: Fax: (602) 364-1150 E-mail: phillik@azdhs.gov

### 10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceeding to obtain oral comment on the adoption of new rules for air ambulance service licensing and air ambulance registration and related time-frames in 9 A.A.C. 25, Articles 7, 8, and 12 (this rulemaking), and the repeal of the rules for ambulance service licensure, ambulance registration certificates, and miscellaneous in 9 A.A.C. 13, Articles 10, 11, and 12 (a concurrent rulemaking):

Date: November 16, 2005

Time: 10:00 a.m.

Location: 150 N. 18th Ave., Room 540A

Phoenix, AZ 85007

Nature: Oral Proceeding

Written comments on the proposed rulemaking or the preliminary economic, small business, and consumer impact summary may be submitted to either individual listed in items #4 and 9 until the close of record at 5:00 p.m. on November 18, 2005.

# 11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

# 12. Incorporations by reference and their location in the rules:

Not applicable

# 13. The full text of the rules follows:

### TITLE 9. HEALTH SERVICES

# CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

# ARTICLE 7. RESERVED AIR AMBULANCE SERVICE LICENSING

Section	
R9-25-701.	Definitions (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)
R9-25-702.	Applicability (A.R.S. §§ 36-2202(A)(4) and 36-2217)
R9-25-703.	Requirement and Eligibility for a License (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-
	2213, 36-2214, and 36-2215)
R9-25-704.	Initial Application and Licensing Process (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-
	<u>2214, and 36-2215)</u>
R9-25-705.	Renewal Application and Licensing Process (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-
	<u>2214, and 36-2215)</u>
R9-25-706.	Term and Transferability of License (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, and 41-
	<u>1092.11)</u>
R9-25-707.	Changes Affecting a License (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)
R9-25-708.	<u>Inspections and Investigations (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, and 36-2214)</u>
R9-25-709.	Enforcement Actions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, 36-2215, 41-1092.03, and
	<u>41-1092.11(B))</u>
R9-25-710.	Minimum Standards for Operations (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)
R9-25-711.	Minimum Standards for Mission Staffing (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)
R9-25-712.	Minimum Standards for Air Ambulance Safety, Equipment, and Supplies (A.R.S. §§ 36-2202(A)(3) and (4),
	36-2209(A)(2), and 36-2213)
R9-25-713.	Minimum Standards for Training (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)
<u>R9-25-714.</u>	Minimum Standards for Communications (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)
R9-25-715.	Minimum Standards for Medical Control (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)
R9-25-716.	Minimum Standards for Recordkeeping (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)
<u>R9-25-717.</u>	Minimum Standards for an Interfacility Neonatal Mission (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2),
	and 36-2213)
<u>R9-25-718.</u>	Minimum Standards for an Interfacility Maternal Mission (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2),
	and 36-2213)

### ARTICLE 8. RECODIFIED AIR AMBULANCE REGISTRATION

Section	
R9-25-801.	Recodified Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2212)
R9-25-802.	Recodified Requirement, Eligibility, and Application for an Initial or Renewal Certificate of Registration for
	an Air Ambulance (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-
	<u>2240(4))</u>
R9-25-803.	Recodified Term and Transferability of Certificate of Registration (A.R.S. §§ 36-2202(A)(4) and (5), 36-
	2209(A)(2), 36-2212, and 41-1092.11)
R9-25-804.	Recodified Changes Affecting Registration (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), and 36-2212)
R9-25-805.	Recodified Inspections (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 36-2232(A)(11))
R9-25-806.	Recodified Enforcement Actions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2212, 36-2234(L), 41-
	1092.03, and 41-1092.11(B))
R9-25-807.	Recodified Minimum Standards for an Air Ambulance (A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2);

and 36-2212)

Table 1. Minimum Equipment and Supplies Required on Air Ambulances, By Mission Level and Aircraft Type (A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212)

#### ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

Section

R9-25-1201. Time-frames (A.R.S. §§ 41-1072 through 41-1079)

Table 1. Time-frames (in days)

#### TITLE 9. HEALTH SERVICES

### **CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES**

#### ARTICLE 7. RESERVED AIR AMBULANCE SERVICE LICENSING

Definitions (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215) In addition to the definitions in A.R.S. § 36-2201, the following definitions apply in this Article and in Article 8 of this Chapter, unless otherwise specified:

- 1. "Advanced life support" means pertaining to a patient whose condition requires care commensurate with the scope of practice of an EMT-P.
- "Air ambulance" means an aircraft that is an "ambulance" as defined in A.R.S. § 36-2201.
- "Air ambulance service" means an ambulance service that operates an air ambulance.
- 4. "Applicant" means an owner requesting:
  - a. An initial or renewal air ambulance service license under Article 7 of this Chapter,
  - An initial or renewal air ambulance certificate of registration under Article 8 of this Chapter, or
  - Transfer of an air ambulance service license under R9-25-706.
- "Basic life support" means pertaining to a patient whose condition requires care commensurate with the scope of practice of an EMT-B.
- "Base location" means a physical location at which a person houses an air ambulance or equipment and supplies used for the operation of an air ambulance service or provides administrative or other support for the operation of an air ambulance service.
- 7. "Business organization" means an entity such as an association, cooperative, corporation, limited liability company, or partnership.
- 8. "CAMTS" means the Commission on Accreditation of Medical Transport Systems, formerly known as the Commission on Accreditation of Air Medical Services.
- 9. "Change of ownership" means a transfer of controlling legal or controlling equitable interest and authority in an air ambulance service.
- 10. "Convalescent transport" means conveyance of a patient at a prearranged time when either the patient's original location or destination is not a health care institution.
- 11. "Critical care" means pertaining to a patient whose condition requires care commensurate with the scope of practice of a physician or registered nurse.
- 12. "Current" means up-to-date and extending to the present time.
- 13. "EMT" means "certified emergency medical technician," as defined in A.R.S. § 36-2201.
- 14. "EMT-B" means "basic emergency medical technician," as defined in A.R.S. § 36-2201.
- 15. "EMT-I" means "intermediate emergency medical technician," as defined in A.R.S. § 36-2201.
- 16. "EMT-P" means "emergency paramedic," as defined in A.R.S. § 36-2201.
- 17. "Estimated time of arrival" means the number of minutes from the time that an air ambulance service agrees to perform a mission to the time that an air ambulance arrives at the scene.
- 18. "Health care institution" has the same meaning as in A.R.S. § 36-401.
  19. "Holds itself out" means advertises through print media, broadcast media, the Internet, or other means.

- 17. Holds itself out lifeals advertises through print fledra, broadcast fledra, the filternet, or other flearis.
  20. "Interfacility" means between two health care institutions.
  21. "Licensed respiratory care practitioner" has the same meaning as in A.R.S. § 32-3501.
  22. "Maternal" means pertaining to a woman whose pregnancy is considered by a physician to be high risk, who is in need of critical care services related to the pregnancy, and who is being transferred to a perinatal center.
- 23. "Medical direction" has the same meaning as in R9-25-101.
- 24. "Medical team" means personnel whose main function on a mission is the medical care of the patient being trans-

- ported.
- 25. "Mission" means a transport job that involves an air ambulance service's sending an air ambulance to a patient's location to provide transport of the patient from one location to another, whether or not transport of the patient is actually provided.
- 26. "Neonatal" means pertaining to an infant who is 28 days of age or younger and who is in need of critical care services.
- 27. "On-line medical direction" has the same meaning as in R9-25-101.
- 28. "On-line medical guidance" means emergency medical services direction or information provided to a non-EMT medical team member by a physician through two-way voice communication.
- 29. "Operate an air ambulance in this state" means:
  - a. Transporting a patient from a location in this state to another location in this state;
  - b. Operating an air ambulance from a base location in this state; or
  - c. Transporting a patient from a location in this state to a location outside of this state more than once per month.
- 30. "Owner" means a person that holds a controlling legal or equitable interest and authority in a business enterprise.
- 31. "Patient" has the same meaning as in R9-25-101.
- 32. "Pediatric" means for use in the treatment of children or other individuals whose size falls within the scope of a pediatric equipment sizing reference guide.
- 33. "Pediatric equipment sizing reference guide" means a chart or device, such as a Broselow™ tape, used to determine the size of medical equipment to be used for a patient who is a child or of small stature, generally based on either patient length or age and weight.
- 34. "Person" means:
  - a. An individual:
  - b. A business organization; or
  - c. An administrative unit of the U.S. government, state government, or a political subdivision of the state.
- 35. "Personnel" means individuals who work for an air ambulance service, with or without compensation, whether as employees, contractors, or volunteers.
- 36. "Premises" means each physical location of air ambulance service operations and includes all equipment and records at each location.
- 37. "Proficiency in neonatal resuscitation" means current and valid certification in neonatal resuscitation obtained through completing a nationally recognized training program such as the American Academy of Pediatrics and American Heart Association NRP: Neonatal Resuscitation Program.
- 38. "Publicizes" means makes a good faith effort to communicate information to the general public through print media, broadcast media, the Internet, or other means.
- 39. "Registered nurse" has the same meaning as in A.R.S. § 32-1601.
- 40. "Regularly" means at recurring, fixed, or uniform intervals.
- 41. "Scene" means the location of the patient to be transported or the closest point to the patient at which an air ambulance can arrive.
- 42. "Subspecialization" means:
  - a. For a physician board certified by a specialty board approved by the American Board of Medical Specialties, subspecialty certification;
  - b. For a physician board certified by a specialty board approved by the American Osteopathic Association, attainment of either a certification of special qualifications or a certification of added qualifications; and
  - c. For a physician who has completed an accredited residency program, completion of at least one year of training pertaining to the specified area of medicine.
- 43. "Two-way voice communication" means that two individuals are able to convey information back and forth to each other orally, either directly or through a third-party relay.
- 44. "Valid" means that a license, certification, or other form of authorization is in full force and effect and not suspended.
- 45. "Working day" means the period between 8:00 a.m. and 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.

### R9-25-702. Applicability (A.R.S. §§ 36-2202(A)(4) and 36-2217)

This Article and Article 8 of this Chapter do not apply to persons and vehicles exempted from the provisions of A.R.S. Title 36, Chapter 21.1 as provided in A.R.S. § 36-2217(A).

# R9-25-703. Requirement and Eligibility for a License (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)

A person shall not operate an air ambulance in this state unless the person has a current and valid air ambulance service license and, except as provided in A.R.S. § 36-2212(C), a current and valid certificate of registration for the air ambulance as required under Article 8 of this Chapter.

- **B.** To be eligible to obtain an air ambulance service license, an applicant shall:
  - 1. Hold current and valid Registration and Exemption under 14 CFR Part 298, as evidenced by a current and valid OST Form 4507 showing the effective date of registration;
  - 2. Hold the following issued by the Federal Aviation Administration:
    - a. A current and valid Air Carrier Certificate authorizing common carriage under 14 CFR Part 135;
    - b. If operating a rotor-wing air ambulance, current and valid Operations Specifications authorizing aeromedical helicopter operations;
    - c. If operating a fixed-wing air ambulance, current and valid Operations Specifications authorizing airplane air ambulance operations;
    - d. A current and valid Certificate of Registration for each air ambulance to be operated; and
    - e. A current and valid Airworthiness Certificate for each air ambulance to be operated;
  - 3. Have applied for a certificate of registration, issued by the Department under Article 8 of this Chapter, for each air ambulance to be operated by the air ambulance service;
  - 4. Hold a current and valid registration, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4, for each air ambulance to be operated by the air ambulance service;
  - 5. Have current and valid liability insurance coverage for the air ambulance service that complies with A.R.S. § 36-2215 and that has at least the following maximum liability limits:
    - a. \$1 million for injuries to or death of any one person arising out of any one incident or accident;
    - b. \$3 million for injuries to or death of more than one person in any one incident or accident; and
    - c. \$500,000 for damage to property arising from any one incident or accident;
  - 6. Have current and valid malpractice insurance coverage for the air ambulance service that complies with A.R.S. § 36-2215 and that has a maximum liability limit of at least \$1 million per occurrence; and
  - 7. Comply with all applicable requirements of this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1.
- C. To maintain eligibility for an air ambulance service license, an air ambulance service shall meet the requirements of subsections (B)(1)-(2) and (4)-(7) and hold a current and valid certificate of registration, issued by the Department under Article 8 of this Chapter, for each air ambulance operated by the air ambulance service.

# R9-25-704. Initial Application and Licensing Process (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, and 36-2215)

- <u>A.</u> To obtain an initial license, an applicant shall submit to the Department an application completed using a Department-provided form and including:
  - 1. The applicant's name, mailing address, fax number, and telephone number;
  - 2. Each business name to be used for the air ambulance service;
  - 3. The physical and mailing addresses to be used for the air ambulance service, if different from the applicant's mailing address:
  - 4. The name, title, address, and telephone number of the applicant's statutory agent or the individual designated by the applicant to accept service of process and subpoenas for the air ambulance service;
  - 5. If the applicant is a business organization:
    - a. The type of business organization;
    - <u>b.</u> The following information about the individual who is to serve as the primary contact for information regarding the application:
      - i. Name;
      - ii. Address;
      - iii. Telephone number; and
      - iv. Fax number, if any;
    - c. The name, title, and address of each officer and board member or trustee; and
    - d. A copy of the business organization's articles of incorporation, articles of organization, or partnership or joint venture documents, if applicable;
  - 6. The name and Arizona license number for the physician who is to serve as the medical director for the air ambulance service;
  - 7. The intended hours of operation for the air ambulance service;
  - 8. The intended schedule of rates for the air ambulance service;
  - 9. The scope of the mission types to be provided, including whether each of the following is to be provided:
    - a. Emergency medical services transports;
    - b. Interfacility transports;
    - c. Interfacility maternal transports;
    - d. Interfacility neonatal transports; and
    - e. Convalescent transports;

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- 10. A copy of a current and valid OST Form 4507 showing the effective date of registration and exemption under 14 CFR Part 298;
- 11. A copy of the following issued by the Federal Aviation Administration:
  - a. A current and valid Air Carrier Certificate authorizing common carriage under 14 CFR Part 135;
  - b. If intending to operate a rotor-wing air ambulance, current and valid Operations Specifications authorizing aeromedical helicopter operations;
  - c. If intending to operate a fixed-wing air ambulance, current and valid Operations Specifications authorizing airplane air ambulance operations;
  - d. A current and valid Certificate of Registration for each air ambulance to be operated; and
  - e. A current and valid Airworthiness Certificate for each air ambulance to be operated;
- 12. For each air ambulance to be operated for the air ambulance service:
  - a. An application for registration that includes all of the information and items required under R9-25-802(C); and
  - b. A copy of a current and valid registration, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4;
- 13. A certificate of insurance establishing that the applicant has current and valid liability insurance coverage for the air ambulance service as required under R9-25-703(B)(5);
- 14. A certificate of insurance establishing that the applicant has current and valid malpractice insurance coverage for the air ambulance service as required under R9-25-703(B)(6):
- 15. If the applicant holds current CAMTS accreditation for the air ambulance service, a copy of the current CAMTS accreditation report;
- 16. Attestation that the applicant knows all applicable requirements in this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1;
- 17. Attestation that the information provided in the application, including the information in the documents accompanying the application form, is accurate and complete; and
- 18. The dated signature of:
  - a. If the applicant is an individual, the individual;
  - b. If the applicant is a corporation, an officer of the corporation;
  - c. If the applicant is a partnership, one of the partners;
  - d. If the applicant is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
  - e. If the applicant is an association or cooperative, a member of the governing board of the association or cooperative;
  - f. If the applicant is a joint venture, one of the individuals signing the joint venture agreement;
  - g. If the applicant is a governmental agency, the individual in the senior leadership position with the agency or an individual designated in writing by that individual; and
  - h. If the applicant is a business organization type other than those described in subsections (A)(18)(b) through (f), an individual who is a member of the business organization.
- B. Unless an applicant establishes that it holds current CAMTS accreditation as provided in subsection (C) or is applying for an initial license because of a change in ownership as described in R9-25-706(D), the Department shall conduct an inspection, as required under A.R.S. § 36-2214(B) and R9-25-708, during the substantive review period for the application for an initial license.
- C. To establish current CAMTS accreditation, an applicant shall submit to the Department a copy of its current CAMTS accreditation report, as provided in subsection (A)(15).
- <u>D.</u> The Department shall review and approve or deny each application as described in Article 12 of this Chapter.
- **E.** The Department may deny an application if an applicant:
  - 1. Fails to meet the eligibility requirements of R9-25-703(B);
  - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
  - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 8 of this Chapter;
  - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department; or
  - 5. Fails to submit to the Department documents or information requested under R9-25-1201(B)(1) or (C)(3), as required under R9-25-1201(D), and requests a denial as permitted under R9-25-1201(E).

# R9-25-705. Renewal Application and Licensing Process (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, and 36-2215)

- A. Before the expiration date of its current license, an air ambulance service shall submit to the Department a renewal application completed using a Department-provided form and including:
  - 1. The information and items listed in R9-25-704(A)(1)-(11), (12)(b), and (13)-(18); and
  - 2. For each air ambulance operated by the air ambulance service:
    - a. A copy of a current and valid certificate of registration issued by the Department under Article 8 of this Chapter;

<u>or</u>

- b. An application for registration that includes all of the information and items required under R9-25-802(C).
- B. Unless an air ambulance service establishes that it holds current CAMTS accreditation as provided in subsection (C), the Department shall conduct an inspection, as required under A.R.S. § 36-2214(B) and R9-25-708, during the substantive review period for the renewal application.
- C. To establish current CAMTS accreditation, an air ambulance service shall submit to the Department, as part of the application submitted under subsection (A), a copy of the air ambulance service's current CAMTS accreditation report.
- **D.** The Department shall review and approve or deny each application as described in Article 12 of this Chapter.
- **E.** The Department may deny an application if an applicant:
  - 1. Fails to meet the eligibility requirements of R9-25-703(C);
  - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
  - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 8 of this Chapter;
  - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department; or
  - 5. Fails to submit to the Department documents or information requested under R9-25-1201(B)(1) or (C)(3), as required under R9-25-1201(D), and requests a denial as permitted under R9-25-1201(E).

# R9-25-706. Term and Transferability of License (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, and 41-1092.11)

- A. The Department shall issue an initial license:
  - 1. When based on current CAMTS accreditation, with a term beginning on the date of issuance and ending on the expiration date of the CAMTS accreditation upon which licensure is based; and
  - 2. When based on Department inspection, with a term beginning on the date of issuance and ending three years later.
- **B.** The Department shall issue a renewal license with a term beginning on the day after the expiration date shown on the previous license and ending:
  - 1. When based on current CAMTS accreditation, on the expiration date of the CAMTS accreditation upon which licensure is based; and
  - 2. When based on Department inspection, three years later.
- C. If an applicant submits an application for renewal as described in R9-25-705 before the expiration date of the current license, the current license does not expire until the Department has made a final determination on the application for renewal, as provided in A.R.S. § 41-1092.11.
- <u>D.</u> A person wanting to transfer an air ambulance service license shall submit to the Department before the anticipated change of ownership:
  - 1. A letter that contains:
    - a. A request that the air ambulance service license be transferred,
    - b. The name and license number of the currently licensed air ambulance service, and
    - c. The name of the person to whom the air ambulance service license is to be transferred; and
  - 2. An application that complies with R9-25-704(A) completed by the person to whom the license is to be transferred.
- E. A new owner shall not operate an air ambulance in this state until the Department has transferred an air ambulance service license to the new owner.

### R9-25-707. Changes Affecting a License (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)

- At least 30 days before the date of a change in an air ambulance service's name, the air ambulance service shall send the Department written notice of the name change.
- **B.** At least 90 days before an air ambulance service ceases to operate, the air ambulance service shall send the Department written notice of the intention to cease operating and the desire to relinquish its license.
- C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
  - 1. For a notice described in subsection (A), issue an amended license that incorporates the name change but retains the expiration date of the current license; and
  - 2. For a notice described in subsection (B), send the air ambulance service written confirmation of the voluntary relinquishment of its license, with an effective date consistent with the written notice.
- **D.** An air ambulance service shall notify the Department in writing within one working day after:
  - 1. A change in its eligibility for licensure under R9-25-703(B) or (C);
  - 2. A change in the business organization information most recently submitted to the Department under R9-25-704(A)(5) or R9-25-705(A);
  - 3. A change in its CAMTS accreditation status, including a copy of its new CAMTS accreditation report, if applicable;
  - 4. A change in its hours of operation or schedule of rates; or
  - 5. A change in the scope of the mission types provided.
- E. Before the date of an anticipated change of ownership, a person wanting to transfer an air ambulance service license shall submit to the Department the documents required under R9-25-706(D).

### R9-25-708. Inspections and Investigations (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, and 36-2214)

- A. Except as provided in subsections (D) and (F), the Department shall inspect an air ambulance service before issuing an initial or renewal license, as required under A.R.S. § 36-2214(B), and as often as necessary to determine compliance with this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1.
- **B.** A Department inspection may include the premises and each air ambulance operated or to be operated for the air ambulance service.
- C. If the Department receives written or verbal information alleging a violation of this Article, Article 2 or 8 of this Chapter, or A.R.S. Title 36, Chapter 21.1, the Department shall conduct an investigation.
  - 1. The Department may conduct an inspection as part of an investigation.
  - 2. An air ambulance service shall allow the Department to inspect the premises and each air ambulance and to interview personnel as part of an investigation.
- D. As required under A.R.S. § 36-2213(8), the Department shall accept proof of current CAMTS accreditation in lieu of the licensing inspections otherwise required before initial and renewal licensure under subsection (A) and A.R.S. § 36-2214(B).
- E. To establish current CAMTS accreditation, an applicant or air ambulance service shall submit to the Department a copy of its current CAMTS accreditation report as required under R9-25-704(C), R9-25-705(C), or R9-25-707(D).
- **E.** When an application for an air ambulance service license is submitted along with a transfer request due to a change of ownership, the Department shall determine whether an inspection is necessary.
- **G** The Department shall conduct each inspection in compliance with A.R.S. § 41-1009.

# R9-25-709. Enforcement Actions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, 36-2215, 41-1092.03, and 41-1092.11(B))

- A. The Department may take an action listed in subsection (B) against an air ambulance service that:
  - 1. Fails to meet the eligibility requirements of R9-25-703(B) or (C);
  - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
  - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 8 of this Chapter; or
  - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department.
- **B.** The Department may take the following actions against an air ambulance service:
  - 1. Except as provided in subsection (B)(3), after notice and an opportunity to be heard is provided under A.R.S. Title 41, Chapter 6, Article 10, suspend the air ambulance service license;
  - 2. After notice and an opportunity to be heard is provided under A.R.S. Title 41, Chapter 6, Article 10, revoke the air ambulance service license; and
  - 3. If the Department determines that the public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summarily suspend the air ambulance service license pending proceedings for revocation or other action, as permitted under A.R.S. § 41-1092.11(B).
- C. In determining whether to take action under subsection (B), the Department shall consider:
  - 1. The severity of each violation relative to public health and safety;
  - 2. The number of violations relative to the transport volume of the air ambulance service;
  - 3. The nature and circumstances of each violation; and
  - 4. Whether each violation was corrected, the manner of correction, and the duration of the violation.

# R9-25-710. Minimum Standards for Operations (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

- A. An air ambulance service shall ensure that:
  - 1. The air ambulance service maintains eligibility for licensure as required under R9-25-703(C);
  - 2. The air ambulance service publicizes its hours of operation:
  - 3. The air ambulance service makes its schedule of rates available to any individual upon request and, if requested, in writing;
  - 4. The air ambulance service provides an accurate estimated time of arrival to the person requesting transport at the time that transport is requested and provides an amended estimated time of arrival to the person requesting transport if the estimated time of arrival changes;
  - 5. The air ambulance service transports only patients for whom it has the resources to provide appropriate medical care, unless subsection (B) or (D) applies;
  - 6. The air ambulance service does not perform interfacility transport of a patient unless:
    - a. The transport is requested by:
      - i. A physician; or
      - ii. A qualified medical person, as determined by the sending health care institution's bylaws or policies, after consultation with and approval by a physician; and
    - b. The destination health care institution confirms that a bed is available for the patient;
  - 7. The air ambulance service creates a prehospital incident history report, as defined in A.R.S. § 36-2220, for each

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### patient;

- 8. The air ambulance service creates a record for each mission that includes:
  - a. Mission date;
  - b. Mission level—basic life support, advanced life support, or critical care;
  - Mission type—emergency medical services transport, interfacility transport, interfacility maternal transport, interfacility neonatal transport, or convalescent transport;
  - d. Aircraft type—fixed-wing aircraft or rotor-wing aircraft;
  - e. Name of the person requesting the transport;
  - f. Time of receipt of the transport request;
  - g. Departure time to the patient's location;
  - h. Address of the patient's location;
  - i. Arrival time at the patient's location;
  - i. Departure time to the destination health care institution;
  - k. Name and address of the destination health care institution;
  - 1. Arrival time at the destination health care institution;
  - m. Patient reference number or call number; and
  - n. Aircraft tail number for the air ambulance used on the mission; and
- 9. The air ambulance service submits to the Department by the 15th day of each month, either in an electronic format approved by the Department or in hard copy, a run log of the previous month's missions that includes the information required under subsections (A)(8)(a)-(d), (f), (g), (i), (j), (l), and (m) in a cumulative tabular format.
- **B.** In a prehospital rescue situation, when no other practical means of transport, including another air ambulance service, is available, an air ambulance service may deviate from subsection (A)(5) to the extent necessary to meet the rescue situation.
- C. An air ambulance service that completes a mission under subsection (B) shall create a record within five working days after the mission, including the information required under subsection (A)(8), the manner in which the air ambulance service deviated from subsection (A)(5), and the justification for operating under subsection (B).
- **D.** An air ambulance service may provide interfacility transport of a patient for which it does not have the resources to provide appropriate medical care if the sending health care institution provides medically appropriate life support measures, staff, and equipment to sustain the patient during the interfacility transport.
- Each staff member provided by a sending health care institution under subsection (D) shall complete training in the subject areas listed in R9-25-713(A) before serving on a mission.

# R9-25-711. Minimum Standards for Mission Staffing (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213) A. An air ambulance service shall ensure that, except as provided in subsection (B):

- 1. Each critical care mission is staffed by a medical team of at least two individuals with at least the following qualifications:
  - a. A physician or registered nurse, and
  - b. An EMT-P or licensed respiratory care practitioner;
- 2. Each advanced life support mission is staffed by a medical team of at least two individuals with at least the following qualifications:
  - a. An EMT-P, and
  - b. Another EMT-P or a licensed respiratory care practitioner; and
- 3. Each basic life support mission is staffed by a medical team of at least two individuals, each of whom has at least the qualifications of an EMT-B.
- B. If the pilot on a mission using a rotor-wing air ambulance determines, in accordance with the air ambulance service's written guidelines required under subsection (C), that the weight of a second medical team member could potentially compromise the performance of the rotor-wing air ambulance and the safety of the mission, and the use of a single-member medical team is consistent with the on-line medical direction or on-line medical guidance received as required under subsection (C), an air ambulance service may use a single-member medical team consisting of an individual with at least the following qualification:
  - 1. For a critical care mission, a physician or registered nurse;
  - 2. For an advanced life support mission, an EMT-P; and
  - 3. For a basic life support mission, an EMT-B.
- C. An air ambulance service shall ensure that:
  - 1. Each air ambulance service rotor-wing pilot is provided written guidelines to use in determining when the weight of a second medical team member could potentially compromise the performance of a rotor-wing air ambulance and the safety of a mission, including the conditions of density altitude and weight that warrant the use of a single-member medical team;
  - 2. The following are done, without delay, after an air ambulance service rotor-wing pilot determines that the weight of a

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second medical team member could potentially compromise the performance of a rotor-wing air ambulance and the safety of a mission:

- a. The pilot communicates that information to the medical team;
- b. The medical team obtains on-line medical direction or on-line medical guidance regarding the use of a single-member medical team; and
- c. The medical team proceeds in compliance with the on-line medical direction or on-line medical guidance;
- 3. A single-member medical team has the knowledge and medical equipment to perform one-person cardiopulmonary resuscitation;
- 4. The air ambulance service has a quality management process to review regularly the patient care provided by each single-member medical team, including consideration of each patient's status upon arrival at the destination health care institution; and
- 5. A single-member medical team is used only when no other transport team is available that would be more appropriate for delivering the level of care that a patient requires.
- D. An air ambulance service that uses a single-member medical team as authorized under subsection (B) shall create a record within five working days after the mission, including the information required under R9-25-710(A)(8), the name and qualifications of the individual comprising the single-member medical team, and the justification for using a single-member medical team.
- E. An air ambulance service shall create and maintain for each personnel member a file containing documentation of the personnel member's qualifications, including, as applicable, licenses, certifications, and training records.

## <u>R9-25-712.</u> <u>Minimum Standards for Air Ambulance Safety, Equipment, and Supplies (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)</u>

An air ambulance service shall ensure that:

- 1. Each air ambulance in use meets the standards in R9-25-807;
- 2. The equipment and supplies on an air ambulance are secured, stored, and maintained in a manner that prevents hazards to personnel and patients; and
- 3. After each mission, an air ambulance's equipment and supplies are checked and replenished as necessary to be in compliance with R9-25-807.

#### R9-25-713. Minimum Standards for Training (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)

- An air ambulance service shall ensure that each medical team member completes training in the following subjects before serving on a mission:
  - 1. Aviation terminology;
  - 2. Physiological aspects of flight;
  - 3. Patient loading and unloading:
  - 4. Safety in and around the aircraft;
  - 5. In-flight communications;
  - 6. Use, removal, replacement, and storage of the medical equipment installed on the aircraft;
  - 7. In-flight emergency procedures;
  - 8. Emergency landing procedures; and
  - 9. Emergency evacuation procedures.
- **B.** An air ambulance service shall document each medical team member's completion of the training required under subsection (A), including the name of the medical team member, each training component completed, and the date of completion.

### R9-25-714. Minimum Standards for Communications (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

An air ambulance service shall ensure that, while on a mission, two-way voice communication is available:

- 1. Between or among personnel on the air ambulance, including the pilot; and
- 2. Between personnel on the air ambulance and the following persons on the ground:
  - a. Personnel;
  - b. Physicians providing on-line medical direction or on-line medical guidance to medical team members; and
  - c. For a rotor-wing air ambulance mission:
    - i. Emergency medical services providers, and
    - ii. Law enforcement agencies.

#### R9-25-715. Minimum Standards for Medical Control (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

- A. An air ambulance service shall ensure that:
  - 1. The air ambulance service has a medical director who:
    - a. Meets the qualifications in subsection (B);
    - b. Supervises and evaluates the quality of medical care provided by medical team members;

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- c. Ensures the competency and current qualifications of all medical team members;
- d. Ensures that each EMT medical team member receives medical direction as required under Article 2 of this Chapter;
- e. Ensures that each non-EMT medical team member receives medical guidance through:
  - i. Written treatment protocols;
  - ii. On-line medical guidance provided by the medical director or another physician designated by the medical director; and
  - iii. If the medical guidance needed exceeds the medical director's area of expertise, on-line medical guidance provided by a consulting specialty physician; and
- <u>Approves, ensures implementation of, and annually reviews treatment protocols to be followed by medical team members:</u>
- 2. The air ambulance service has a quality management program through which:
  - a. Data related to patient care and transport services provided and patient status upon arrival at destination are:
    - i. Collected continuously, and
    - ii. Examined regularly, on at least a quarterly basis; and
  - b. Appropriate corrective action is taken when concerns are identified; and
- 3. The air ambulance service documents each concern identified through the quality management program and the corrective action taken to resolve each concern and provides this information, along with the supporting data, to the Department upon request.

#### **B.** A medical director shall:

- 1. Be a physician, as defined in A.R.S. § 36-2201; and
- 2. Comply with one of the following:
  - a. If the air ambulance service provides emergency medical services transports, meet the qualifications of A.A.C. R9-25-204(A)(2);
  - b. If the air ambulance service does not provide emergency medical services transports, meet the qualifications of A.A.C. R9-25-204(A)(2) or one of the following:
    - i. If the air ambulance service provides only interfacility maternal missions, have board certification or have completed an accredited residency program in one of the following specialty areas:
      - (a) Obstetrics and gynecology, with subspecialization in critical care medicine or maternal and fetal medicine; or
      - (b) Pediatrics, with subspecialization in neonatal-perinatal medicine;
    - ii. If the air ambulance service provides only interfacility neonatal missions, have board certification or have completed an accredited residency program in one of the following specialty areas:
      - (a) Obstetrics and gynecology, with subspecialization in maternal and fetal medicine; or
      - (b) Pediatrics, with subspecialization in neonatal-perinatal medicine, neonatology, pediatric critical care medicine, or pediatric intensive care; or
    - iii. If neither subsection (B)(2)(b)(i) or (ii) applies, have board certification or have completed an accredited residency program in one of the following specialty areas:
      - (a) Anesthesiology, with subspecialization in critical care medicine;
      - (b) Internal medicine, with subspecialization in critical care medicine;
      - (c) If the air ambulance service transports only pediatric patients, pediatrics, with subspecialization in pediatric critical care medicine or pediatric emergency medicine; or
      - (d) If the air ambulance service transports only surgical patients, surgery, with subspecialization in surgical critical care.

#### R9-25-716. Minimum Standards for Recordkeeping (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)

An air ambulance service shall retain each document required to be created or maintained under this Article or Article 2 or 8 of this Chapter for at least three years after the last event recorded in the document and shall produce each document for Department review upon request.

## R9-25-717. Minimum Standards for an Interfacility Neonatal Mission (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

An air ambulance service shall ensure that:

- 1. Each interfacility neonatal mission is staffed by a medical team of individuals that complies with the requirements for a critical care mission medical team in R9-25-711(A)(1) and that has the following additional qualifications:
  - a. Proficiency in pediatric emergency care, as defined in R9-25-101; and
  - b. Proficiency in neonatal resuscitation and stabilization of the neonatal patient;
- 2. Each interfacility neonatal mission is conducted using an air ambulance that has the equipment and supplies required for a critical care mission in Table 1 of Article 8 of this Chapter and the following:

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- a. A transport incubator with:
  - i. Battery and inverter capabilities,
  - ii. An infant safety restraint system, and
  - iii. An integrated neonatal-capable pressure ventilator with oxygen-air supply and blender;
- b. An invasive automatic blood pressure monitor;
- c. A neonatal monitor or monitors with heart rate, respiratory rate, temperature, non-invasive blood pressure, and pulse oximetry capabilities;
- d. Neonatal specific drug concentrations and doses;
- e. Umbilical catheter insertion equipment and supplies;
- f. Thoracostomy supplies;
- g. Neonatal resuscitation equipment and supplies;
- h. A neonatal size cuff (size 2, 3, or 4) for use with an automatic blood pressure monitor; and
- i. A neonatal probe for use with a pulse oximeter;
- 3. On-line medical direction or on-line medical guidance provided to an interfacility neonatal mission medical team member is provided by a physician who meets the qualifications of R9-25-715(B)(2)(b)(ii); and
- 4. An individual is not permitted to serve on an interfacility neonatal mission medical team until the air ambulance service's medical director has verified and attested in writing to the individual's having the proficiencies described in subsections (1)(a) and (b).

## R9-25-718. Minimum Standards for an Interfacility Maternal Mission (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

- A. This Section applies to an air ambulance service that holds itself out as providing interfacility maternal missions.
- **B.** An air ambulance service shall ensure that:
  - 1. Each interfacility maternal mission is staffed by a medical team of individuals that complies with the requirements for a critical care mission medical team in R9-25-711(A)(1) and that has the following additional qualifications:
    - a. Proficiency in advanced emergency cardiac life support, as defined in R9-25-101;
    - b. Proficiency in neonatal resuscitation; and
    - c. <u>Proficiency in stabilization and transport of the maternal patient;</u>
  - 2. Each interfacility maternal mission is conducted using an air ambulance that has the equipment and supplies required for a critical care mission in Table 1 of Article 8 of this Chapter and the following:
    - a. A Doppler fetal heart monitor;
    - b. Unless use is not indicated for the patient as determined through on-line medical direction or on-line medical guidance provided as described in subsection (B)(3), an external fetal heart and tocographic monitor with printer capability;
    - c. Tocolytic and anti-hypertensive medications;
    - d. Advanced emergency cardiac life support equipment and supplies; and
    - e. Neonatal resuscitation equipment and supplies;
  - 3. On-line medical direction or on-line medical guidance provided to an interfacility maternal mission medical team member is provided by a physician who meets the qualifications of R9-25-715(B)(2)(b)(i); and
  - 4. An individual is not permitted to serve on an interfacility maternal mission medical team until the air ambulance service's medical director has verified and attested in writing to the individual's having the proficiencies described in subsections (B)(1)(a), (b), and (c).

#### ARTICLE 8. RECODIFIED AIR AMBULANCE REGISTRATION

#### R9-25-801. Recodified Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2212)

In addition to the definitions in R9-25-701, the following definitions apply in this Article, unless otherwise specified:

- 1. "Certificate holder" means a person who holds a current and valid certificate of registration for an air ambulance.
- 2. "Drug" has the same meaning as in A.R.S. § 32-1901.

# R9-25-802. Recodified Requirement, Eligibility, and Application for an Initial or Renewal Certificate of Registration for an Air Ambulance (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2240(4))

- A. A person shall not operate an air ambulance in this state unless the person has a current and valid air ambulance service license as required under Article 7 of this Chapter and, except as provided in A.R.S. § 36-2212(C), a current and valid certificate of registration for the air ambulance as required under this Article.
- **B.** To be eligible to obtain a certificate of registration for an air ambulance, an applicant shall:
  - 1. Hold a current and valid air ambulance service license issued under Article 7 of this Chapter;
  - 2. Hold the following issued by the Federal Aviation Administration for the air ambulance:

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- a. A current and valid Certificate of Registration, and
- b. A current and valid Airworthiness Certificate;
- 3. Hold a current and valid registration for the air ambulance, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4; and
- 4. Comply with all applicable requirements of this Article, Articles 2 and 7 of this Chapter, and A.R.S. Title 36, Chapter 21.1.
- C. To obtain an initial or renewal certificate of registration for an air ambulance, an applicant shall submit to the Department an application completed using a Department-provided form and including:
  - 1. The applicant's name, mailing address, fax number, and telephone number;
  - 2. All other business names used by the applicant;
  - 3. The applicant's physical business address, if different from the mailing address;
  - 4. The following information about the air ambulance for which registration is sought:
    - a. Each mission level for which the air ambulance will be used:
      - i. Basic life support,
      - ii. Advanced life support, or
      - iii. Critical care;
    - b. Whether a fixed-wing or rotor-wing aircraft;
    - c. Number of engines;
    - d. Manufacturer name;
    - e. Model name;
    - f. Year manufactured;
    - g. Serial number;
    - h. Aircraft tail number;
    - i. Aircraft colors, including fuselage, stripe, and lettering; and
    - i. A description of any insignia, monogram, or other distinguishing characteristics of the aircraft's appearance;
  - 5. A copy of the following issued to the applicant, for the air ambulance, by the Federal Aviation Administration:
    - a. A current and valid Certificate of Registration, and
    - b. A current and valid Airworthiness Certificate:
  - 6. A copy of a current and valid registration issued to the applicant, for the air ambulance, by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4;
  - 7. The location in Arizona at which the air ambulance will be available for inspection;
  - 8. The name and telephone number of the individual to contact to arrange for inspection, if the inspection is preannounced;
  - 9. Attestation that the applicant knows all applicable requirements in A.R.S. Title 36, Chapter 21.1; this Article; and Articles 2 and 7 of this Chapter;
  - 10. Attestation that the information provided in the application, including the information in the documents accompanying the application form, is accurate and complete;
  - 11. The dated signature of:
    - a. If the applicant is an individual, the individual;
    - b. If the applicant is a corporation, an officer of the corporation;
    - c. If the applicant is a partnership, one of the partners;
    - d. If the applicant is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
    - e. If the applicant is an association or cooperative, a member of the governing board of the association or cooperative;
    - f. If the applicant is a joint venture, one of the individuals signing the joint venture agreement;
    - g. If the applicant is a governmental agency, the individual in the senior leadership position with the agency or an individual designated in writing by that individual; and
    - h. If the applicant is a business organization type other than those described in subsections (C)(11)(b) through (f), an individual who is a member of the business organization; and
  - 12. Unless the applicant operates or intends to operate the air ambulance only as a volunteer not-for-profit service, a certified check, business check, or money order made payable to the Arizona Department of Health Services for the following fees:
    - a. A \$50 registration fee, as required under A.R.S. § 36-2212(D); and
    - b. A \$200 annual regulatory fee, as required under A.R.S. § 36-2240(4).
- <u>D.</u> The Department requires submission of a separate application and fees for each air ambulance.
- Except as provided under R9-25-805(C), the Department shall inspect each air ambulance to determine compliance with the provisions of A.R.S. Title 36, Chapter 21.1 and this Article before issuing an initial certificate of registration and at least every 12 months thereafter before issuing a renewal certificate of registration.

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- <u>F.</u> The Department shall review and approve or deny each application as described in Article 12 of this Chapter.
- **G.** The Department may deny a certificate of registration for an air ambulance if the applicant:
  - 1. Fails to meet the eligibility requirements of R9-25-802(B);
  - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
  - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 7 of this Chapter;
  - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department; or
  - 5. Fails to submit to the Department documents or information requested under R9-25-1201(B)(1) or (C)(3), as required under R9-25-1201(D), and requests a denial as permitted under R9-25-1201(E).

## R9-25-803. Recodified Term and Transferability of Certificate of Registration (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 41-1092.11)

- **<u>A.</u>** The Department shall issue an initial certificate of registration:
  - 1. With a term of one year from date of issuance; or
  - 2. If requested by the applicant, with a term shorter than one year that allows for the Department to conduct annual inspections of all of the applicant's air ambulances at one time.
- **B.** The Department shall issue a renewal certificate of registration with a term of one year.
- C. If an applicant submits an application for renewal as described in R9-25-802 before the expiration date of the current certificate of registration, the current certificate of registration does not expire until the Department has made a final determination on the application for renewal, as provided in A.R.S. § 41-1092.11.
- **<u>D.</u>** A certificate of registration is not transferable from one person to another.
- **E.** If there is a change in the ownership of an air ambulance, the new owner shall apply for and obtain a new certificate of registration before operating the air ambulance in this state.

## R9-25-804. Recodified Changes Affecting Registration (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), and 36-2212)

- At least 30 days before the date of a change in a certificate holder's name, the certificate holder shall send the Department written notice of the name change.
- **B.** No later than 10 days after a certificate holder ceases to operate an air ambulance, the certificate holder shall send the Department written notice of the desire to relinquish the certificate of registration for the air ambulance.
- C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
  - 1. For a notice described in subsection (A), issue an amended certificate of registration that incorporates the name change but retains the expiration date of the current certificate of registration; and
  - 2. For a notice described in subsection (B), send the certificate holder written confirmation of the voluntary relinquishment of the certificate of registration, with an effective date that corresponds to the written notice.
- <u>D.</u> A certificate holder shall notify the Department in writing within one working day after a change in its eligibility to obtain a certificate of registration for an air ambulance under R9-25-802(B).

#### R9-25-805. Recodified Inspections (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 36-2232(A)(11))

- An applicant or certificate holder shall make an air ambulance available for inspection within Arizona at the request of the Department.
- **B.** The Department shall conduct each inspection in compliance with A.R.S. § 41-1009.
- C. As permitted under A.R.S. § 36-2232(A)(11), upon certificate holder request and at certificate holder expense, the annual inspection of an air ambulance required for renewal of a certificate of registration may be conducted by a Department-approved inspection facility.

## R9-25-806. Recodified Enforcement Actions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2212, 36-2234(L), 41-1092.03, and 41-1092.11(B))

- A. The Department may take an action listed in subsection (B) against a certificate holder's certificate of registration if the certificate holder:
  - 1. Fails or has failed to meet the eligibility requirements of R9-25-802(B);
  - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
  - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 7 of this Chapter; or
  - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department.
- **B.** The Department may take the following actions against a certificate holder's certificate of registration:
  - 1. After notice and an opportunity to be heard is provided under A.R.S. Title 41, Chapter 6, Article 10, revoke the certificate of registration; and
  - 2. In case of emergency, if the Department determines that a potential threat to the public health and safety exists and incorporates a finding to that effect in its order, immediately suspend the certificate of registration as authorized under A.R.S. § 36-2234(L).

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- C. In determining whether to take action under subsection (B), the Department shall consider:
  - 1. The severity of each violation relative to public health and safety;
  - 2. The number of violations relative to the transport volume of the air ambulance service;
  - 3. The nature and circumstances of each violation; and
  - 4. Whether each violation was corrected, the manner of correction, and the duration of the violation.

## R9-25-807. Recodified Minimum Standards for an Air Ambulance (A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212)

- A. An applicant or certificate holder shall ensure that an air ambulance has:
  - 1. A climate control system to prevent temperature extremes that would adversely affect patient care;
  - 2. If a fixed-wing air ambulance, pressurization capability;
  - 3. Interior lighting that allows for patient care and monitoring without interfering with the pilot's vision;
  - 4. For each patient position, at least one electrical power outlet or other power source that is capable of operating all electrically powered medical equipment without compromising the operation of any electrical aircraft equipment;
  - 5. A back-up source of electrical power or batteries capable of operating all electrically powered life-support equipment for at least one hour;
  - 6. An entry that allows for patient loading and unloading without rotating a patient and stretcher more than 30 degrees about the longitudinal axis or 45 degrees about the lateral axis and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation;
  - 7. A configuration that allows each medical team member sufficient access to each patient to begin and maintain treatment modalities, including complete access to the patient's head and upper body for effective airway management;
  - 8. A configuration that allows for rapid exit of personnel and patients, without obstruction from stretchers and medical equipment;
  - 9. A configuration that protects the aircraft's flight controls, throttles, and communications equipment from any intentional or accidental interference from a patient or equipment and supplies;
  - 10. A padded interior or an interior that is clear of objects or projections in the head strike envelope;
  - 11. An installed self-activating emergency locator transmitter;
  - 12. A voice communications system that:
    - a. Is capable of air-to-ground communication, and
    - b. Allows the flight crew and medical team members to communicate with each other during flight;
  - 13. Interior patient compartment wall and floor coverings that are:
    - a. Free of cuts or tears,
    - b. Capable of being disinfected, and
    - c. Maintained in a sanitary manner; and
  - 14. If a rotor-wing air ambulance, the following:
    - a. A searchlight that:
      - i. Has a range of motion of at least 90 degrees vertically and 180 degrees horizontally,
      - ii. Is capable of illuminating a landing site, and
      - iii. Is located so that the pilot can operate the searchlight without removing the pilot's hands from the aircraft's flight controls;
    - b. Restraining devices that can be used to prevent a patient from interfering with the pilot or the aircraft's flight controls; and
    - c. A light to illuminate the tail rotor.
- **B.** An applicant or certificate holder shall ensure that:
  - 1. Except as provided in subsection (C), each air ambulance has the equipment and supplies required in Table 1 for each mission level for which the air ambulance is used; and
  - 2. The equipment and supplies on an air ambulance are secured, stored, and maintained in a manner that prevents hazards to personnel and patients.
- C. A certificate holder may conduct an interfacility critical care mission using an air ambulance that does not have all of the equipment and supplies required in Table 1 for the mission level if:
  - 1. Care of the patient to be transported necessitates use of life-support equipment that because of its size or weight or both makes it unsafe or impossible for the air ambulance to carry all of the equipment and supplies required in Table 1 for the mission level, as determined by the certificate holder based upon individual aircraft capabilities, size and weight of the equipment and supplies required in Table 1 and of the additional life-support equipment, the composition of the required medical team; and environmental factors such as density altitude;
  - 2. The certificate holder ensures that during the mission the air ambulance has the equipment and supplies necessary to provide an appropriate level of medical care for the patient and to protect the health and safety of the personnel on the mission;
  - 3. The certificate holder ensures that, during the mission, the air ambulance is not directed by the air ambulance service

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- or another person to conduct another mission before returning to a base location;
- 4. The certificate holder ensures that the air ambulance is not used for another mission until the air ambulance has all of the equipment and supplies required in Table 1 for the mission level; and
- 5. Within five working days after each interfacility critical care mission conducted as permitted under subsection (C), the certificate holder creates a record that includes the information required under R9-25-710(A)(8), a description of the life-support equipment used on the mission, a list of the equipment and supplies required in Table 1 that were removed from the air ambulance for the mission, and the justification for conducting the mission as permitted under subsection (C).

## Table 1. Minimum Equipment and Supplies Required on Air Ambulances, By Mission Level and Aircraft Type (A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212)

X = Required

ALS = Advanced Life Support Mission

BLS = Basic Life Support Mission

CC = Critical Care Mission

FW = Fixed-Wing Aircraft

RW = Rotor-Wing Aircraft

<u>M</u>	ININ	IUM EQUIPMENT AND SUPPLIES	<u>FW</u>	RW	BLS	ALS	CC
<u>A.</u>	Ven	tilation and Airway Equipment					
	<u>1.</u>	Portable and fixed suction apparatus, with wide-bore tubing, rigid pharyngeal curved suction tip, tonsillar and flexible suction catheters, 5F-14F	X	X	X	X	X
	<u>2.</u>	Portable and fixed oxygen equipment, with variable flow regulators	X	X	X	X	X
	<u>3.</u>	Oxygen administration equipment, including tubing; non-rebreathing masks (adult and pediatric sizes); and nasal cannulas (adult and pediatric sizes)	X	X	X	X	<u>X</u>
	<u>4.</u>	Bag-valve mask, with hand-operated, self-reexpanding bag (adult size), with oxygen reservoir/accumulator; mask (adult, pediatric, infant, and neonate sizes); and valve	X	X	X	X	X
	<u>5.</u>	Airways, oropharyngeal (adult, pediatric, and infant sizes)	<u>X</u>	<u>X</u>	<u>X</u>	X	<u>X</u>
	<u>6.</u>	Laryngoscope handle with extra batteries and bulbs, adult and pediatric	X	X	=	X	X
	<u>7.</u>	Laryngoscope blades, sizes 0, 1, and 2, straight; sizes 3 and 4, straight and curved	X	X	=	X	X
	<u>8.</u>	Endotracheal tubes, sizes 2.5-5.0 mm uncuffed and 6.0-8.0 mm cuffed	X	X	=	X	X
	<u>9.</u>	Meconium aspirator	<u>X</u>	<u>X</u>	=	<u>X</u>	<u>X</u>
	<u>10.</u>	10 mL straight-tip syringes	<u>X</u>	<u>X</u>	=	<u>X</u>	<u>X</u>
	<u>11.</u>	Stylettes for Endotracheal tubes, adult and pediatric	<u>X</u>	<u>X</u>	=	<u>X</u>	<u>X</u>
	<u>12.</u>	Magill forceps, adult and pediatric	<u>X</u>	<u>X</u>	=	X	X
	<u>13.</u>	Nasogastric tubes, sizes 5F and 8F, Salem sump sizes 14F and 18F	X	X	=	X	X
	<u>14.</u>	End-tidal CO <sub>2</sub> detectors, colorimetric or quantitative	X	X	=	X	X

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М	ININ	MUM EQUIPMENT AND SUPPLIES	<u>FW</u>	RW	BLS	ALS	CC
		Portable automatic ventilator with positive end expiratory pressure	X	X	=	X	<u>X</u>
<u>B.</u>	Mo	onitoring and Defibrillation					
	1.	Automatic external defibrillator	X	X	X	=	=
	<u>2.</u>	Portable, battery-operated monitor/defibrillator, with tape write-out/recorder, defibrillator pads, adult and pediatric paddles or hands-free patches, ECG leads, adult and pediatric chest attachment electrodes, and capability to provide electrical discharge below 25 watt-seconds	X	X	=	X	X
	<u>3.</u>	Transcutaneous cardiac pacemaker, either stand-alone unit or integrated into monitor/defibrillator	X	X	Ξ	X	X
<u>C.</u>	<u>Im</u>	mobilization Devices					
	<u>1.</u>	Cervical collars, rigid, adjustable or in an assortment of adult and pediatric sizes	=	X	X	X	X
	2. Head immobilization device, either firm padding or another commercial device		=	X	X	X	X
	3. Lower extremity (femur) traction device, including lower extremity, limb support slings, padded ankle hitch, padded pelvic support, and traction strap		=	X	X	X	X
	<u>4.</u>	Upper and lower extremity immobilization splints	Ξ	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>
<u>D.</u>	Bar	<u>ndages</u>					
	<u>1.</u>	Burn pack, including standard package, clean burn sheets	<u>X</u>	<u>X</u>	X	<u>X</u>	<u>X</u>
	<u>1.</u> <u>2.</u>	Burn pack, including standard package, clean burn sheets  Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges	<u>X</u> <u>X</u>	<u>X</u> <u>X</u>	<u>X</u> <u>X</u>	<u>X</u> <u>X</u>	<u>X</u> <u>X</u>
		Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4"					
	<u>2.</u>	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges	X	X	X	X	X
	<u>2.</u> <u>3.</u>	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)	<u>X</u>	<u>X</u>	<u>X</u> <u>X</u>	<u>X</u>	<u>X</u>
	2. 3. 4. 5.	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)	<u>X</u> <u>X</u> <u>X</u>	<u>X</u> <u>X</u> <u>X</u>	<u>X</u> <u>X</u> <u>X</u>	<u>X</u> <u>X</u> <u>X</u>	X X X
<u>E.</u>	2. 3. 4. 5. 6.	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)  Occlusive dressing, sterile, 3" x 8" or larger  Adhesive tape, including various sizes (1" or larger) hypoaller-	X X X X	<u>X</u> <u>X</u> <u>X</u> <u>X</u>	X X X X	<u>X</u> <u>X</u> <u>X</u> <u>X</u> <u>X</u>	<u>X</u> <u>X</u> <u>X</u> <u>X</u> <u>X</u>
<u>E.</u>	2. 3. 4. 5. 6.	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)  Occlusive dressing, sterile, 3" x 8" or larger  Adhesive tape, including various sizes (1" or larger) hypoallergenic and various sizes (1" or larger) adhesive	X X X X	<u>X</u> <u>X</u> <u>X</u> <u>X</u>	X X X X	<u>X</u> <u>X</u> <u>X</u> <u>X</u> <u>X</u>	<u>X</u> <u>X</u> <u>X</u> <u>X</u> <u>X</u>
<u>E.</u>	2. 3. 4. 5. 6.	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)  Occlusive dressing, sterile, 3" x 8" or larger  Adhesive tape, including various sizes (1" or larger) hypoallergenic and various sizes (1" or larger) adhesive  stetrical  Obstetrical kit (separate sterile kit), including towels, 4" x 4" dressing, umbilical tape, sterile scissors or other cutting utensil, bulb suction, clamps for cord, sterile gloves, at least 4 blankets,	X X X X X	X X X X X	X	X X X X X	X
<u>E.</u>	2. 3. 4. 5. 6. Ob	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)  Occlusive dressing, sterile, 3" x 8" or larger  Adhesive tape, including various sizes (1" or larger) hypoallergenic and various sizes (1" or larger) adhesive  stetrical  Obstetrical kit (separate sterile kit), including towels, 4" x 4" dressing, umbilical tape, sterile scissors or other cutting utensil, bulb suction, clamps for cord, sterile gloves, at least 4 blankets, and a head cover	X X X X X	X	X	X	X
	2. 3. 4. 5. 6. Ob	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)  Occlusive dressing, sterile, 3" x 8" or larger  Adhesive tape, including various sizes (1" or larger) hypoallergenic and various sizes (1" or larger) adhesive  stetrical  Obstetrical kit (separate sterile kit), including towels, 4" x 4" dressing, umbilical tape, sterile scissors or other cutting utensil, bulb suction, clamps for cord, sterile gloves, at least 4 blankets, and a head cover  An alternate portable patient heat source or 2 heat packs	X X X X X	X	X	X	X
	2.	Dressings, including sterile multi-trauma dressings (various large and small sizes); ABDs, 10" x 12" or larger; and 4" x 4" gauze sponges  Gauze rolls, sterile (4" or larger)  Elastic bandages, non-sterile (4" or larger)  Occlusive dressing, sterile, 3" x 8" or larger  Adhesive tape, including various sizes (1" or larger) hypoallergenic and various sizes (1" or larger) adhesive  stetrical  Obstetrical kit (separate sterile kit), including towels, 4" x 4" dressing, umbilical tape, sterile scissors or other cutting utensil, bulb suction, clamps for cord, sterile gloves, at least 4 blankets, and a head cover  An alternate portable patient heat source or 2 heat packs  scellaneous  Sphygmomanometer (infant, pediatric, and adult regular and	X	X	X	X	X

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M	INIMUM EQUIPMENT AND SUPPLIES	<u>FW</u>	RW	BLS	ALS	<u>CC</u>
	5. Hazardous material reference guide	X	X	X	X	<u>X</u>
	6. Hearing protection for patient and personnel	X	X	X	X	X
<u>I.</u>	Vascular Access					
	1. Intravenous administration equipment, with fluid in bags	X	X	=	X	X
	2. Antiseptic solution (alcohol wipes and povidone-iodine wipes)	<u>X</u>	X	=	X	<u>X</u>
	3. Intravenous pole or roof hook X		X	=	X	<u>X</u>
	4. Intravenous catheters 14G-24G		X	=	X	<u>X</u>
	5. <u>Intraosseous needles</u>	X	X	=	<u>X</u>	<u>X</u>
	6. Venous tourniquet	X	X	=	X	X
	<ul> <li>One of each of the following types of intravenous solution administration sets:</li> <li>a. A set with blood tubing.</li> <li>b. A set capable of delivering 60 drops per cc, and</li> <li>c. A set capable of delivering 10 or 15 drops per cc</li> </ul>	X	X	Ξ	X	X
	8. Intravenous arm boards, adult and pediatric	<u>X</u>	<u>X</u>	=	<u>X</u>	<u>X</u>
	9. IV pump or pumps (minimum of 3 infusion lines)	<u>X</u>	X	=	X	<u>X</u>
	10. IV pressure bag	<u>X</u>	X	=	X	<u>X</u>
<u>J.</u>	. Medications					
	1. Drugs and drug-related equipment required in the EMT-B Drug List in Exhibit 1 to R9-25-503	X	X	X	=	=
	2. Drugs and drug-related equipment required in the EMT-P and Qualified EMT-I Drug List in Exhibit 1 to R9-25-503	X	X	=	X	X

#### ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

### R9-25-1201. Time-frames (A.R.S. §§ 41-1072 through 41-1079)

- A. No change
- **B.** No change
  - 1. No change
  - 2. No change
  - 3. No change
- C. No change
  - 1. As part of the substantive review time-frame for an application for an approval other than renewal of an ambulance registration, the Department shall conduct inspections, conduct investigations, or hold hearings required by law.
  - 2. No change
  - 3. No change
  - 4. No change
  - 5. No change6. No change
- **D.** No change
- E. No change
- F. No change

Time-frames (in days) Table 1.

Type of Application	Statutory Authority	Overall Time- frame	Administrative Completeness Time-frame	Time to Respond to Written Notice	Substantive Review Time-frame	Time to Respond to Comprehensive Written Request
ALS Base Hospital Certification (R9-25-208)	A.R.S. §§ 36-2201, 36-2202(A)(3), and 36-2204(5)	45	15	60	30	60
Amendment of an ALS Base Hospital Certificate (R9-25-209)	A.R.S. §§ 36-2201, 36-2202(A)(3), and 36-2204(5) and (6)	30	15	60	15	60
Training Program Certification (R9-25-302)	A.R.S. §§ 36-2202(A)(3) and 36-2204(1) and (3)	120	30	60	90	60
Amendment of a Training Program Certificate (R9-25-303)	A.R.S. §§ 36-2202(A)(3) and 36-2204(1) and (3)	90	30	60	60	60
EMT Certification (R9-25-404)	A.R.S. §§ 36-2202(A)(2), (3), and (4), 36-2202(G), and 36-2204(1)	120	30	90	90	270
Temporary Nonrenewable EMT-B or EMT-P Certifi- cation (R9-25-405)	A.R.S. §§ 36-2202(A)(2), (3), and (4), 36-2202(G), and 36-2204(1) and (7)	120	30	90	90	60
EMT Recertification (R9-25-406)	A.R.S. §§ 36-2202(A)(2), (3), (4), and (6), 36-2202(G), and 36-2204(1) and (4)	120	30	60	90	60
Extension to File for EMT Recertification (R9-25-407)	A.R.S. §§ 36-2202(A)(2), (3), (4), and (6), 36-2202(G), and 36-2204(1) and (7)	30	15	60	15	60
Downgrading of Certification (R9-25-408)	A.R.S. §§ 36-2202(A)(2), (3), and (4), 36-2202(G), and 36-2204(1) and (6)	30	15	60	15	60
Initial Air Ambulance Service License (R9-25-704)	A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, 36-2215, and 41-1841	150	30	60	120	60
Renewal of an Air Ambulance Service License (R9-25-705)	A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, 36- 2215, and 41-1841	90	30	60	<u>60</u>	60
Transfer of an Air Ambulance Service License (R9-25-706)	A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, and 41-1092.11	<u>150</u>	30	<u>60</u>	120	<u>60</u>
Initial Certificate of Registration for an Air Ambulance (R9-25-802)	A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2240(4)	90	30	60	60	60
Renewal of a Certificate of Registration for an Air Ambulance (R9-25-802)	A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2240(4)	90	30	<u>60</u>	<u>60</u>	<u>60</u>

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Initial Certificate of Necessity (R9-25-902)	A.R.S. §§ 36-2204, 36-2232, 36-2233, 36-2240	450	30	60	420	60
Provision of ALS Services (R9-25-902)	A.R.S. §§ 36-2232, 36-2233, 36-2240	450	30	60	420	60
Transfer of a Certificate of Necessity (R9-25-902)	A.R.S. §§ 36-2236(A) and (B), 36-2240	450	30	60	420	60
Renewal of a Certificate of Necessity (R9-25-904)	A.R.S. §§ 36-2233, 36-2235, 36-2240	90	30	60	60	60
Amendment of a Certificate of Necessity (R9-25-905)	A.R.S. §§ 36-2232(A)(4), 36-2240	450	30	60	420	60
Initial Registration of a Ground Ambulance Vehicle (R9-25-1001)	A.R.S. §§ 36-2212, 36-2232, 36-2240	90	30	60	60	60
Renewal of a Ground Ambulance Vehicle Registration (R9-25-1001)	A.R.S. §§ 36-2212, 36-2232, 36-2240	90	30	60	60	60
Establishment of Initial General Public Rates (R9-25-1101)	A.R.S. §§ 36-2232, 36-2239	450	30	60	420	60
Adjustment of General Public Rates (R9-25-1102)	A.R.S. §§ 36-2234, 36-2239	450	30	60	420	60
Contract Rate or Range of Rates Less than General Public Rates (R9-25- 1103)	A.R.S. §§ 36-2234, 36-2239	450	30	60	420	60
Ground Ambulance Service Contracts (R9-25-1104)	A.R.S. § 36-2232	450	30	60	420	60
Ground Ambulance Service Contracts with Political Subdivisions (R9-25-1104)	A.R.S. §§ 36-2232, 36-2234(K)	30	15	15	15	Not Applicable
Subscription Service Rate (R9-25-1105)	A.R.S. § 36-2232(A)(1)	450	30	60	420	60
Air Ambulance Registration Certificate (R9-13-1101)	A.R.S. § 36-2212	90	30	60	60	60
Air Ambulance Registration Certificate Renewal (R9-13-1101)	A.R.S. § 36-2212	90	30	60	60	60